

**CODEX COMMITTEE ON
NUTRITION AND FOODS FOR
SPECIAL DIETARY USES
28th SESSION**

**U.S. DRAFT POSITIONS
As of
September 8, 2006**

U.S. PRELIMINARY DRAFT Positions for the 28th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/12/06 U.S. Stakeholders Public Meeting

Notice to U.S. Interested Parties in the Activities of the Codex Committee on Nutrition and Foods for Special Dietary Uses

The next session of this Codex committee will be held in Chiang Mai, Thailand from October 30 to November 3, 2006. In addition, an *ad hoc* working group will meet on October 28 from 9:30 a.m. to 5:30 p.m. to review comments and proposals on infant formula composition. Dr. Barbara Schneeman will head the U.S. delegation.

This document identifies U.S. preliminary draft positions as of September 8, 2006 on the agenda items for the 28th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). The agenda for the 28th session is posted at the following web address, along with reference documents on each agenda item as they become available:

<http://www.codexalimentarius.net/web/current.jsp?lang=en>

As identified in a previous communication, a public meeting will be held on September 12, 2006 from 1:00 p.m. to 4:00 p.m. in College Park, Maryland in order to provide information and receive public comments on the agenda items that will be discussed at the next CCNFSDU session and on U.S. draft positions (Please refer to the August 22, 2006 Federal Register Notice, Vol. 71, No. 162, pp. 48907-09). Note: If you plan to attend this public meeting, please download from the above web site the CCNFSDU documents for reference.

We also invite you to submit written comments by September 27, 2006. Please direct these to: CCNFSDU@fda.gov. We request comments by this date to facilitate their consideration in preparing final draft U.S. positions for the Bonn meeting. We also invite you to submit a copy of your comments to the U.S. Department of Agriculture public docket for the public meeting (See above Federal Register notice for details).

**MATTERS REFERRED
BY THE CODEX ALIMENTARIUS COMMISSION
AND/OR OTHER CODEX COMMITTEES**

AGENDA ITEM No. 2

BACKGROUND

Reference:

- CX/NFSDU 06/28/2 (Matters Referred) and related documents *not yet available*

The Committee is invited to consider matters referred to it by the Codex Alimentarius Commission and/or by other Committees. The above reference document will be based on information prepared by the Codex Secretariat.

The United States anticipates that one of the issues that will again be referred is the role of Codex Alimentarius Committees in implementing the WHO Global Strategy on Diet, Physical Activity and Health (Global Strategy).

The 28th Session of the Codex Alimentarius Commission agreed to ask WHO, in cooperation with FAO, to prepare a document to be focused on actions that could be taken by Codex to facilitate the implementation of the Global Strategy for consideration by the Codex Committee on Food Labelling (CCFL) and Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). This issue was introduced at the last CCFL and CCNFSDU sessions. Comments from Codex Members (including the United States) and Observers to questions posed by WHO and FAO were posted on the WHO website in April, and were summarized for the 29th Session of the Commission in July (CAC/29 LIM/6). The Commission agreed that WHO and FAO would complete a document containing concrete proposals for possible actions by Codex that would shortly be circulated for comments to all Codex Contact Points. The comments received together with the document itself would then be considered by the next sessions of the CCNFSDU and CCFL, and the views and recommendations of these Committees then forwarded to the 30th Session of the Commission for further guidance (ALINORM 06/29/41, para 176).

DRAFT POSITION

The United States has not yet received CCNFSDU reference document(s) on matters referred, and consequently has not formulated a draft position on the content. In the interim, the United States offers a few general comments on the role of Codex in implementing the Global Strategy based on preliminary comments submitted to the WHO/FAO e-Forum and further discussion at the 34th CCFL Session.

The U.S. emphasizes the need for CCNFSDU and CCFL to conduct an in-depth analysis of the issues which considers, among other things, the relationship between the Codex mandate and the Global Strategy goal and objectives, the terms of reference of these two Codex Committees and

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their past and future work, the voluntary nature of Codex standards, and the appropriateness of actions at the global versus national/regional levels.

For example, “protection of consumers” health appears to be one area of overlap between the Codex mandate and Global Strategy goal, with labeling activities identified as an important interface between the two. Specifically, the WHO and FAO discussion paper at the last Commission meeting noted that provisions for nutrition labelling and label claim statements would enhance the consumer’s opportunity to select a healthy diet and thereby promote an “environment” that would support actions to reduce chronic diseases (CAC/29 LIM/6, para 9). The United States notes that past and current work of CCFL and CCNFSDU with labeling provisions and their scientific basis already plays a role in the implementation of the Global Strategy (including current work on the scientific basis for health claims), but that the Committees now have an opportunity to identify possible areas for new work which may further both Codex and Global Strategy goals (e.g., amendments related to nutrition labeling provisions).

The U.S supports efforts to prioritize future Codex work on nutrition issues, including standards for foods for special dietary uses as well as Codex texts that are applied “horizontally”, with priority given to work that is most likely to further the goal of protecting consumers’ health. The U.S. further supports efforts to enhance coordination between the WHO/FAO and Codex in the identification of scientific advice needs and priorities related to nutrients and related substances via WHO/FAO expert consultations and other means.

The U.S. anticipates that it will have additional comments on the subject of Codex and the Global Strategy and additional topics raised in the matters referred document(s) at the upcoming CCNFSDU session.

**GUIDELINES FOR THE USE OF NUTRITION CLAIMS:
DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS
(PART B CONTAINING PROVISIONS ON DIETARY FIBRE
AT STEP 6)**

AGENDA ITEM No. 3

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, paras 14-28; Appendix III)
- Comments at Step 6 CX/NFSDU 06/28/3
- CX/NFSDU 04/3-Add 1 (July 2004)

At the last meeting, the Committee agreed to return the draft provisions on dietary fiber as amended during the 27th Session of the CCNFSDU (See Appendix III).

Definition and properties of dietary fibre. After some discussion at the last meeting, the Committee agreed to include text to clarify that a degree of polymerization (DP) not lower than 3 is intended to exclude mono- and disaccharides and is not intended to reflect the average DP of a mixture. The Committee also agreed to identify the physiological properties of dietary fiber and the need for a physiological effect to be scientifically demonstrated by appropriate studies except for naturally occurring dietary fiber. The Secretariat noted the need to decide on the title and placement of the “Recommendations to Codex Committees Using this Definition of Dietary Fibre”.

Methods of Analysis The Committee agreed that methods of analysis would be considered at the next session using the list already compiled in CX/NFSDU 04/3-Add.1.

Conditions for Dietary Fibre Claims At the last meeting, the Committee discussed whether conditions for dietary fibre content claims should be provided for liquid foods and discussed other aspects of the conditions, and invited further comments at the next session.

Please refer to the above documents for additional background.

DRAFT POSITION

I. GENERAL COMMENTS

Our comments address:

- Definition and Properties of Dietary Fibre
- Recommendations to Codex Committees Using this Definition of Dietary Fibre
- Methods of Analysis for Dietary Fibre
- Draft Table of Conditions for Dietary Fibre Content Claims

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The above topics are currently identified in Appendix III of ALINORM 06/29/26 which is entitled, “Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B) Dietary Fibre (at Step 6 of the Procedure)”. It may be helpful to review at the next session the specific charge of the CCNFSDU relative to the above topics and the specific Codex texts in which these recommendations would eventually be placed. This clarification may help the Committee finalize its recommendations on these topics.

Specifically, the United States requests confirmation that the CCNFSDU intends to propose to CCFL that the Definition and Properties of Dietary Fiber replace the existing text in Section 2.7 of the Codex *Guidelines on Nutrition Labelling*, and that the table of conditions for dietary fibre content claims be added to the “Table of Conditions for Nutrient Contents” in the *Guidelines for Use of Nutrition and Health Claims*. As discussed below, the United States also notes the need to clarify the placement of 1) recommendations to Codex Committees using the proposed definition of dietary fibre, and 2) methods of analysis for dietary fibre.

II. SPECIFIC COMMENTS

Definition and Properties of Dietary Fibre

Definition:

The United States notes that the Committee could not come to a conclusion at the last session as to whether footnote 1 should be retained in the definition section or moved to a section on methods of analysis (ALINORM 06/29/26, para 18). As another option, we propose that the Committee consider placing this text in the section on Recommendations to Codex Committees Using this Definition of Dietary Fibre.

If the Committee decides to retain this text, we propose the following edits:

¹ When derived from a plant origin, dietary fibre may include fractions of lignin and/ or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC **Enzymatic Gravimetric** analytical method for dietary fibre analysis: Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re- introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. ~~When combined with polysaccharides, these associated substances may provide additional beneficial effects.~~

Rationale:

- We recommend adding “Enzymatic” to refer to the proper name of this method.
- We recommend deleting the last sentence because text about possible beneficial effects of certain substances falls outside the scope of the Definition section. Properties of dietary fiber are addressed in a separate section.

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We further suggest that the Committee consider the following edit to the first bullet:

~~Edible~~ carbohydrate polymers naturally occurring in the **edible portions of** food as consumed,

Rationale: We believe the intent is for “edible” to refer to food rather than to carbohydrate polymers.

Editorial comment:

- The square bracket symbol in the first sentence of the Definition section can be deleted.

Properties:

The United States proposes the following edit for clarification:

Dietary fibre generally has **one or more** properties such as:

Recommendations to Codex Committees Using this Definition of Dietary Fibres

The United States proposes that the Committee consider deleting the second bullet or revising it as follows:

~~“The physiological effects listed in the definition~~ **properties of dietary fibre** may vary with the substances present in the foods and the justification for the use of ~~the nutrition and health claims~~ **about specific properties** must accommodate this diversity.

Rationale:

We are uncertain about the intended meaning of this bullet (e.g., what is meant by “the justification ... must accommodate this diversity”). If this bullet is retained, we propose at a minimum the above edits to: 1) use consistent terminology, and 2) clarify that such justification would need to be provided only for health claims about specific properties of dietary fiber, and not for nutrient content claims that do not refer to specific properties.

The United States further notes the need to clarify where these recommendations will be placed (ALINORM 06/29/26, para 22).

Editorial Comment:

If the title for this section on recommendations is retained, the United States suggests that “Dietary Fibres” be changed to “Dietary Fibre” for consistency.

Methods of Analysis for Dietary Fibre

The United States offers the following comments on the methods of analysis section in CX/NFSDU 04/3—Add. 1.

We note that all proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed (Codex Procedural Manual, 15th ed., p. 73), and that the Codex Secretariat identified the need for further clarification relative to corresponding Codex provisions at the last CCNFSDU session (ALINORM 06/29/26, para 20). Accordingly, with regard to the eventual placement of the table on methods of analysis for dietary fiber, the United States requests clarification from the Secretariat as to whether it would be appropriate for the CCNFSDU to propose to CCFL that the final table be placed in a new section in the Codex *Guidelines on Nutrition Labelling*, or alternatively, whether there is a need to create a separate Codex standard on general methods of analysis for nutrients (considering for example the format of an existing standard such as the General Methods of Analysis for Contaminants (CODEX STAN 228-2001, Rev. 1, 2004)). Irrespective of the table's eventual placement, the U.S. proposes that the Committee consider a format that identifies the applicability of the official methods to all foods or a subset, and that the information be presented in a way that it will not soon become out of date.

In addition, the draft table of methods should be reviewed for consistency with the Codex definition.

Draft Table of Conditions for Dietary Fibre Content Claims

Basis for Dietary Fiber Content Claims

The United States continues to support inclusion of serving size as a basis for expressing dietary fiber content claims, and emphasizes the importance that the criteria be based on scientific recommendations for daily dietary fiber intake.

Accordingly, we propose that the Committee consider expressing conditions for dietary fiber claims in a similar manner as the 2001 amendments to the Table of Conditions of Nutrient Contents in the *Guidelines for Use of Nutrition and Health Claims* which specifies conditions for “source” and “high” claims for protein, vitamins and minerals as a percentage of a daily reference value (CAC/GL 23-1997, Rev. 2-2004). Specifically, these guidelines express the conditions as a specified percentage of the Nutrient Reference Value (NRV) per 100 g, per 100 ml, per 100 kcal, or per serving.

This would not only promote consistency with recent approaches, but might also promote transparency in identifying the relationship between the criteria and recommendations for daily dietary fiber intake. In addition, it should obviate the need to update this table if a Nutrient Reference Value for dietary fiber is established or subsequently updated.

Accordingly, we propose that the Committee consider the option of revising the table in Appendix III as follows:

COMPONENT	CLAIM	CONDITIONS
B.		
NOT LESS THAN		
Dietary Fibre	Source	[__% of daily reference value ¹ per 100 g (solids) __% of daily reference value per 100 ml (liquids) or __% of daily reference value per 100 kcal or 10% of daily reference value per serving ²]
	High	2 times the value for “source”

¹ A daily reference value may be either a Codex Nutrient Reference Value for food labelling purposes (that may be established in the future) or a value determined at the national level based on science-based recommended daily intakes taking into account additional factors specific to a country or region.

² Serving size to be determined at the national level.

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In addition, we request clarification on the status of the planned FAO/WHO expert consultation on carbohydrate requirements, and on how this work may relate to CCNFSDU's consideration of scientific recommendations for daily intake of dietary fiber and to the possible future establishment of a Nutrient Reference Value.

**DRAFT REVISED STANDARD FOR INFANT FORMULA
AND FORMULAS FOR SPECIAL MEDICAL PURPOSES
INTENDED FOR INFANTS AT STEP 6: SECTION A**

AGENDA ITEM No. 4a

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, paras 64-111, Appendix IV A)
- Comments at Step 6 CX/NFSDU 06/28/4 (excludes Sections 3 and 4)
- CX/NFSDU 06/28/4- Add.3: Proposals of the Working Group on Section 3 (Prepared by Germany)
- Conference Room Document (CRD) 1: Revised Section 3 proposal for discussion at CCNFSDU plenary session
(*will result from 10/28/06 ad hoc working group meeting*)
- Section 4 food additive proposal prepared by Switzerland for discussion at CCNFSDU plenary session (CX/NFSDU 06/28/4-Add. 2) *not yet available*

At the last meeting, the Committee agreed to return Section A for comments and consideration at the next session.

General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula. At the last meeting, the Committee agreed with the amended principles in 3, 4, 5 and 7 and to include all the principles as an Annex to the draft revised standard for infant formula.

Section 3.1 (Essential Composition) After much discussion of the draft provisions in Section 3.1, the Committee agreed to keep the entire section in square brackets and asked the Electronic Working Group chaired by Germany to look especially at discrepancies between the proposed maximum values and the amounts of nutrients currently used in infant formula in member countries. The Committee asked ESPGHAN to provide an opinion on the discrepancies. The Observer from ISDI proposed to submit global data for currently applied maximum values for infant formula. The Committee also agreed that a physical Working Group would be convened before the next session to review comments and proposals for compositional requirements.

Section 4 (Food Additives) The Committee did not discuss this section at the last meeting due to time constraints. It accepted the offer of the Delegation of Switzerland to prepare a revised list of additives taking into account the proposals made by CCFAC on Section 4 for the Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children and comments submitted to the current session. The Committee also agreed that an Electronic Working Group coordinated by Switzerland would look at all additives that may need to be included in section B taking into account comments received.

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Labelling, Methods of Analysis, and Other Sections. The Committee did not discuss other sections of the draft revised standard at the last meeting due to time constraints.

Please refer to the above documents for additional background.

DRAFT POSITION ON ANNEX II: GENERAL PRINCIPLES FOR ESTABLISHING MINIMUM AND MAXIMUM VALUES FOR THE ESSENTIAL COMPOSITION OF INFANT FORMULA

Comment: The Chair of the Electronic Working Group has indicated that it may be necessary to reopen discussion of Annex II because of differences in interpretation of maximum and GULs by individual countries. The Committee reached agreement on the General Principles at the 27th session of CCNFSDU. The U.S. has proposed added language for footnote 1 to clarify that the purpose of the GULs is to provide guidance to manufacturers and that GULs should not be interpreted as goal values. The added language further explains that when a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs. The United States believes that this added language addresses the issues raised by differences in interpretation by member states and that the discussion of Annex II need not be reopened.

DRAFT POSITION ON THE REVISED SECTION 3 PROPOSAL PREPARED BY GERMANY

I. GENERAL COMMENTS

Comment: We are in agreement with the overall organization of Section 3 and with the content of 3.1.1, 3.1.2, 3.3, 3.4, 3.5, and 3.6 as presented in Section A of Appendix IV of ALINORM 06/29/26.

Comment: We continue to believe that maximum values should be set only in cases where data are sufficient to support a science-based risk assessment.

Comment: We are including the following paragraphs to explain the rationale for our recommendations for guidance upper levels (GULs). It should be kept in mind that the purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

Based on the wide variability in ranges of nutrient values in infant formulas, we question whether it is appropriate to apply numbers for cows' milk-based powdered infant formula to other formulas (e.g., liquid cows' milk-based formulas, formulas based on other mammalian milks, or soy-protein based formulas). Because GULs provide information that is not equivalent to maximum values for nutrients in infant formulas established by science-based risk assessment and because of the variability in the data and the factors that contribute to this variability, we also questioned how these values will be used.

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Because of these questions, we earlier identified three options for strategies to move forward in further consideration of GUL:

1. GUL may be very specific in coverage: i.e., careful specification of the products the GUL apply to (and those they don't apply to) and the setting of numbers that are specific to the type(s) and forms of products covered
2. GUL may be very general in coverage: i.e., setting numbers high enough to accommodate all types and all forms of infant formulas
3. National legislation may be another option for setting GUL, given that there are substantive differences in regulatory requirements among countries. The role of Codex would be to provide principles for individual countries to set GUL that take into account their markets and their regulations.

The Chair has pointed out that setting GULs in accordance with national legislation may result in difficulties in international trade. Although we continue to think that setting GULs corresponding to national legislation is an option, we agree that the implications of implementing this option should be considered very carefully.

The 2005 International Expert Group (IEG) report proposed maximum values for nutrients in infant formulas based on scientific data where available and on values derived on the basis of meeting the nutritional needs of infants (multiples of the minimum values). As the IEG report did not reflect information on history of apparently safe use, the infant formula industry (specifically ISDI) offered to provide analytical information on the levels of nutrients found in infant formulas at product release to provide a basis for a history of safe use. The ISDI report was sent to the Electronic Working Group for evaluation in March 2006.

The differences between IEG and ISDI values were substantive for a number of vitamins and minerals. To better understand the factors contributing to the differences in values in the ISDI report and the IEG values, the U.S. Delegate requested additional information from the U.S. infant formula industry. Analyses of release values for formulas manufactured and marketed in the U.S. were prepared by the International Formula Council (IFC). The IFC analyses provided information by protein sources (milk and soy) and forms (powders and liquids).

Based on our assessment of the reports from ISDI and IFC, there are several important technical and manufacturing reasons for the variations found in the levels of nutrients in infant formula:

- Form (liquid vs. powder)
- Inherent levels and variability of the nutrients in ingredients
- Nutrient stability over shelf life
- Analytical variability (within and between laboratories)
- Other technical considerations:
 - Effects of packaging, container material, or container size

- Effects of processing.

No single factor explained the variability that contributes to the differences between IEG and ISDI levels. Taken together, the number of factors affecting variability illustrated the difficulty of establishing upper levels for nutrients that are not based on scientific risk assessment.

Examination of the IFC analyses by type and form of infant formula revealed that the maximum levels for cow milk protein powder (MP) were closer to the levels recommended by the IEG than maximum levels for other forms and protein source (i.e., soy) for the majority of the nutrients identified in the ISDI report. When MP mean + 2 SD values are compared to the IEG values, there are 3 vitamins (niacin, biotin, and vitamin B12) and 2 minerals (iron and copper) that are notably different. Given the similarity of the IEG proposed maximum values with only the MP mean + 2SD values, the IEG values do not appear to consider history of apparently safe use for all types and forms of infant formula currently marketed worldwide. The IEG proposed maximum values are not consistent with the scope in Section A (1.1) of the standard, which states “This section of the standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants”.

The ISDI values for the upper end of the range of means + 2 SD are generally the same or close to the IFC values for infant formulas manufactured and marketed in the U.S. To accommodate the variability contributed by the factors listed above and to be consistent with the principles and the scope of the Infant Formula Standard Section A, we propose that the GULs be set at the upper end of the range of the mean + 2 standard deviations (SD) for each nutrient. GULs set on this basis take into account the sources of variation for all types and forms of infant formulas. Tolerances for analytical variability in products will also need to be taken into account.

Several sources of information support the concept that these values may appropriately be assigned as GULs. For example, in the U.S., growth of infants is routinely monitored in health care settings and surveillance systems are in place to monitor the nutritional status of low-income infants. In addition, the nutrient content of each batch of finished infant formula is analyzed by the manufacturer and products that do not meet the U.S. regulations for nutrient composition are not released into the market. Regular inspections of infant formula plants by FDA include confirmation that infant formula that enters the marketplace meets national specifications for nutrient composition. Finally, there is a mechanism for tracking of complaints by U.S. infant formula manufacturers and FDA inspection of complaint records. Taken together, the information available from these sources supports the concept that the proposed GULs are consistent with a history of apparently safe use.

In cases where the Committee cannot reach agreement on GULs, the Committee could alternatively employ the approach used for the current Infant Formula Standard (CODEX STAN 72-1981 (amended 1983, 1985, 1987, 1997)), i.e., using the designation “N.S.”

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rather than setting a numerical value for all nutrients. Specifically, the current standard identified maximum levels for only five nutrients because there was insufficient evidence to set maximum levels for other nutrients. We also note that inadequate levels of nutrients rather than high levels appear to have been the source of problems with infant formulas.

II. SPECIFIC COMMENTS ON TABLE 3.1.3

We wish to clarify a point with respect to earlier U.S. comments. The numbers presented by the U.S. Delegate at the 27th Session of the CCNFSDU were identified in ALINORM 06/29/26 as U.S. proposals for GULs for certain nutrients. These values were intended to illustrate that differences existed between the International Expert Group (IEG) values and commercial infant formulas and were not intended as proposed GUL values. The comments submitted in this draft position include our proposals for the GUL values for individual nutrients and the reasons for proposing the particular values.

We continue to believe that Table 3.1.3 should include separate columns for Maximum and Guidance Upper Levels to make it clear that the two types of values are different.

We are submitting the following comments on specific sections of Table 3.1.3.

Footnote 1:

¹ Guidance upper levels (**GULs**) are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of **apparently** safe use. They may be adjusted based on relevant scientific or technological progress. **The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.**

Comment: We propose the added text for footnote 1 to clarify and emphasize the purpose of GULs. We believe that addition of this language will alleviate the need to reopen the discussion of Annex II.

a) Protein ² (g)

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Protein ^{3,4}	g/100 kcal	1.8	3	
	g/100 kJ	0.45	0.7	

²⁾ ~~[For the purpose of this standard, the calculation of the protein content should be based on N x 6.25 unless a scientific justification is provided for the use of a different conversion factor for a~~

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~~particular nitrogen source.] The protein levels set in this standard are based on the nitrogen conversion factor of 6.25.~~

Footnote 2:

² The value of 6.38 is established as a specific factor appropriate for conversion of nitrogen to protein for cows milk in Codex milk product standards. In the absence of an established nitrogen conversion factor for a protein source, a factor of 6.25 may used.

Comment: We propose rewording of footnote 2 as shown above.

Rationale: Upon reviewing the comments from other countries and the Chair's synopsis, we are concerned that there may be differing interpretations on the nitrogen conversion factor (NCF) as currently presented in footnote 2. It is important to keep in mind that the NCF is a factor for calculating the amount (quantity) of protein. The Chair has correctly identified the two issues with regard to the NCF. It is possible to address the Chair's point regarding conversion of nitrogen to protein accretion in infants by using a general factor of 6.25. The nitrogen in a specific protein source to meet that requirement should be converted by a factor specific to that protein source when a specific factor is available.

Our understanding was that specific NCF values should be used when already established for specific ingredients (e.g., 6.38 for milk proteins). Only when a specific NCF has not been established, should the general NCF, 6.25, be used to calculate protein content. Applying the general NCF, 6.25, when specific factors are available is not consistent with scientific principles or other Codex standards. We proposed the removal of the square brackets when we thought the specific factors would be used as consistent with the other Codex commodity standards. However, given that the current wording may be interpreted differently, we believe the footnote needs to be reworded to remove any ambiguity.

The use of the 6.38 NCF for milk proteins is supported by other Codex standards. For example, Codex standards using an NCF of 6.38 include whey powders (Codex Standard A15 – 1995 Rev. 1 – 2003), edible casein products (Codex Standard A18 – 1995 – Rev. 1 – 2001), evaporated milks (Codex Standard A3 – 1971 Rev. 1 – 1999), and milk powders (Codex Standard A5 – A 10). The Codex Committee on Milk and Milk Products also stated its continued support of the 6.38 NCF at its recent meeting (ALINORM 06/29/11, para 17):

17. The Committee had already established the use of 6.38 as the nitrogen conversion factor in all milk product standards adopted by the Commission addressing protein content and this had support in the scientific literature. The Committee reiterated its position that there is a need for a consistent application of the conversion factor used for the calculation of milk protein throughout Codex and the Committee continues to support the nitrogen conversion factor of 6.38 as scientifically justified.

The scientific literature suggests that use of 5.71 as a specific NCF is appropriate for soy protein. However, this specific factor is not applied consistently in Codex standards. For example, the general factor of 6.25 is used as the NCF in CODEX STAN 175-1989, the general standard for soy protein products. This may need to be reexamined by the appropriate Codex committee(s).

³ [Infant formulae based on non-hydrolyzed cows' milk protein containing less than 2 g protein/100 kcal and infant formula based on **partially** hydrolyzed protein containing less than 2.25 g protein/100 kcal should be clinically evaluated.]

Comment: We continue to stress the need to distinguish between infant formulas containing proteins that are partially hydrolyzed versus those that contain extensively hydrolyzed proteins. Extensively hydrolyzed infant formulas are formulas for special medical purposes for use in infants who are allergic to cow milk proteins. Extensively hydrolyzed proteins derived from cows' milk contain most of the nitrogen in the form of free amino acids and peptides less than 1500 kDa in size. In contrast to extensively hydrolyzed proteins, partially hydrolyzed proteins can have a median molecular weight of about 1500 kDa; however, a significant portion of the protein or peptides in these formulas can have a molecular weight greater than 1500 kDa. This distribution can contain protein fragments and peptides of 5000 kDa or larger. Formulas based on partially hydrolyzed cows' milk proteins formulas are not for use for the dietary management of infants with cows' milk allergy as any formula with intact cows' milk proteins and large peptides may provoke reactions in infants allergic to cows' milk proteins. Therefore, formulas containing partially hydrolyzed proteins are appropriately included in Part A of the infant formula standard and formulas based on extensively hydrolyzed proteins are appropriately included in Part B.

⁴ Minimum values apply to cows' milk protein. For infant formula based on non-cows' milk protein, other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.7 g/100 kJ) applies.

- 3.1.4 For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of methionine and cysteine and of tyrosine and phenylalanine may be added together. ~~[unless the methionine to cysteine or the phenylalanine to tyrosine ratio are outside the range of 0.7-1.5:1]~~

Editorial Comment: We suggest incorporating this statement as a footnote to the protein section of Table 3.1.3 rather than inserting a separately numbered item into the Table.

Comment: The amino acids and values listed in Annex I (Essential and semi-essential amino acids in breast milk) appear to be the same as in the draft revised standard before

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the 2005 recommendations from the IEG. Please clarify whether this list of amino acids and values is now being proposed for the draft revised standard.

Comment: This comment addressed the values for amino acid levels in Table 5 of the 2005 IEG report and proposed for incorporation into the draft revised standard in CRD 14 (Agenda Item 6 for the Twenty-seventh Session of CCNFSDU). The amino acid levels as presented in Table 4 of the 2005 IEG report demonstrate the considerable variation of amino acid composition of human milk and the considerable variation in analytical values obtained with different methods of amino acid analysis. Methods of amino acid analysis have changed over time and data obtained by newer methods may not be directly comparable to data generated by methods used earlier. For example, older methods of analysis overestimated the amount of tryptophan and cystine/cysteine. Because the analytical values obtained are, in part, dependent on the methodology used for analysis, we recommend use of a more comprehensive table such as Table 4 in the IEG report, which lists values that can be linked to specific methods of analysis, rather than a summary table such as Table 5 from the IEG report or the present list of amino acids and values in Annex I. If a more comprehensive table of ranges is used, manufacturers and government agencies can compare their analytical results to values that were obtained by comparable methodology. With the large amount of variation in human milk and in methodology for determination of amino acids, we remain reluctant to support the adoption of an average amino acid pattern for protein quality evaluation for infant formulas and question whether there are clinical studies to support recommendation of an average amino acid pattern in the infant formula matrix.

Comment: We suggest that the phrase [unless the methionine to cysteine or the phenylalanine to tyrosine ratio are outside the range of 0.7-1.5:1] be deleted.

Rationale: The recommendation of this ratio is based on one study of parenterally fed piglets and a report of a new approach for setting amino acid requirements using measurements of amino acid oxidation, a technique that has not been fully validated and has apparently not been applied to children younger than 3 years of age. In the case of the methionine and cysteine, the ratio inherent to cows' milk protein (casein:whey 82:18) is typically around 3:1 and the ratio of these amino acids in casein-dominant formulas is outside the range proposed in 3.1.4. Casein-dominant infant formulas have been marketed in the United States for many years with no evidence of inadequacy of protein or essential amino acids. Footnote 3 for Table 3.1.3 a includes the provision that infant formulas containing less than 2 g protein/100 kcal . . . should be clinically evaluated. These studies will provide a better way of evaluating whether there is a need for addition of cysteine to specific infant formulas than application of the proposed range of methionine:cysteine ratios to all formulas. In the case of phenylalanine and tyrosine, the ratio of phenylalanine to tyrosine in whey is 1.09:1 and in casein is 0.85:1. It is clear that any formula based on cows' milk, regardless of the whey to casein ratio, will fall within the range of 0.7:1 to 1.7:1. Thus, there seems to be no reason to include this ratio in the standard.

3.1.5 Isolated amino acids may be added to infant formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms shall be used.

Editorial Comment: We suggest incorporating this statement as a footnote to the protein section of Table 3.1.3 rather than inserting a separately numbered item into the Table.

b) Lipids

Total fat ⁵ (g)

Commercially hydrogenated oils and fats shall not be used in infant formulas.

Editorial Comment: We suggest that this statement be incorporated into footnote 5 as shown below.

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Total fat	g/100k cal	4.4	6.0	
	g/100 kJ	1.05	1.4	

⁵ Lauric and myristic acids are constituents of fats, but combined should not exceed 20% of [total fatty acids]. The content of trans fatty acids shall not be higher than [3%] of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to [3%] of trans fatty acids is intended to allow for the use of milk fat in infant formulae. The erucic acid content shall be less than 1% of total fatty acids. **Commercially hydrogenated oils and fats shall not be used in infant formulas.**

Linoleic acid

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Linoleic acid	g/100k cal	0.3	4.2	1.6
	g/100 kJ	0.07	0.3	0.38

Comment: We support a GUL for linoleic acid because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formula. The value proposed for the GUL takes into consideration the variability of linoleic acid among product forms (liquids and powders) and inherent variability of linoleic acid in oils used as ingredients in infant formulas.

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Linolenic acid

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Linolenic acid	g/100k cal	50	N.S.	
	g/100 kJ	12	N.S.	

Ratio linoleic acid/ α -linolenic acid

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Ratio linoleic/ α -linolenic acid		5:1	15:1	
		5:1	15:1	

c) Total carbohydrates⁶

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Total carbohydrates	g/100 kcal	9.0	14.0	
	g/100 kJ	2.2	3.3	

⁶ Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and **partially** hydrolyzed protein. Only precooked and/or gelatinized starches may be added to infant formula up to 30% of total carbohydrates or up to 2g/100 ml. [Sucrose, unless needed, and addition of fructose, **as an ingredient**, ~~particularly~~ should be avoided in infant formula because of potential life-threatening symptoms in young infants with unrecognized hereditary fructose intolerance.]

Comment: Although we recognize the serious nature hereditary fructose intolerance and the medical need to restrict sources of fructose in infants with this disorder, we are puzzled by the proposed restriction for formulas for healthy infants. If this language is maintained, it is essential to add the phrase "as an ingredient" because ingredients such as corn syrup solids and oligosaccharides, which may be added to some formulas, may contain some monosaccharides.

Comment: We believe the word "partially" should be added to the first sentence to differentiate between infant formulas based on partially and extensively hydrolyzed proteins. Please see detailed comment on footnote 3.

d) Vitamins

Vitamin A ($\mu\text{g RE}^7$)

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin A	$\mu\text{g RE}/100 \text{ kcal}$	60	480	225
	$\mu\text{g RE}/100 \text{ kJ}$	14	43	54

⁷ Expressed as retinol equivalents (RE). $1 \mu\text{g RE} = 3.33 \text{ IU vitamin A} = 1 \mu\text{g all-trans retinol}$. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Comment: We support a GUL for vitamin A because data are not sufficient for a science-based risk assessment to establish a maximum value for vitamin A consumed in food (i.e., infant formulas). The United States has a history of safe use with a maximum of $225 \mu\text{g RE}/100 \text{ kcal}$. The GUL proposed value takes into consideration variability of vitamin A among product forms (liquids and powders), losses over shelf life, and a history of apparently safe use.

Vitamin D₃ (μg^8)

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin D ₃	$\mu\text{g}/100 \text{ kcal}$	1	2.5	
	$\mu\text{g}/100 \text{ kJ}$	0.25	0.6	

⁸ Calciferol. $1 \mu\text{g calciferol} = 40 \text{ IU vitamin D}$.

Vitamin E ($\text{mg } \alpha\text{-TE}^9$)

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin E	$\text{mg } \alpha\text{-TE}/100 \text{ kcal}$	0.5^{10}		5
	$\text{mg } \alpha\text{-TE}/100 \text{ kJ}$	0.12		1.2

⁹ $1 \text{ mg } \alpha\text{-TE}$ (alpha tocopherol equivalent) = $1 \text{ mg d-}\alpha\text{-tocopherol}$

¹⁰ Vitamin E content shall be at least $0.5 \text{ mg } \alpha\text{-TE}$ per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: $0.5 \text{ mg } \alpha\text{-TE/g linoleic acid (18:2 n-6)}$; $0.75 \text{ mg } \alpha\text{-TE/g linoleic acid (18:3 n-3)}$; $1.0 \text{ mg } \alpha\text{-TE/g arachidonic acid (20:4 n-6)}$; $1.25 \text{ mg } \alpha\text{-TE/g eicosapentaenoic acid (20:5 n-3)}$; $1.5 \text{ mg } \alpha\text{-TE/g docosahexaenoic acid (22:6 n-3)}$.

Comment: The United States supports the proposed GUL for vitamin E and we agree with the content of footnotes 9 and 10.

Vitamin K

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin K	$\mu\text{g}/100 \text{ kcal}$	4		25 30
	$\mu\text{g}/100 \text{ kJ}$	1		6 7

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Comment: We support a GUL for vitamin K because data are not sufficient for a science-based risk assessment to establish a maximum value. The value proposed for the GUL takes into consideration inherent variability of vitamin K in oils used as ingredients in infant formulas, analytical variability for vitamin K measurement, and history of apparently safe use.

Thiamin

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Thiamin	µg/ 100 kcal	60		300 340
	µg/ 100 kJ	14		72 80

Comment: We support a GUL for thiamin because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The value proposed for the GUL takes into consideration variability among product forms (liquids and powders), losses over shelf life, and history of apparently safe use.

Riboflavin

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Riboflavin	µg/ 100 kcal	80		400 520
	µg/ 100 kJ	19		100 120

Comment: We support a GUL for riboflavin because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The value proposed for the GUL takes into consideration variability among product forms (liquids and powders), inherent variability of riboflavin in milk-derived ingredients used in infant formulas, losses over shelf life, and history of apparently safe use.

Niacin ¹¹(µg)

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Niacin	µg/ 100 kcal	300		1500 2600
	µg/ 100 kJ	70		360 630

¹¹Niacin refers to preformed niacin.

Comment: We support a GUL for niacin because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The value proposed for the GUL takes into consideration variability among product forms (liquids and powders), losses over shelf life, and history of apparently safe use.

Vitamin B6

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin B6	µg/ 100 kcal	35		175
	µg/ 100 kJ	8.5		45

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Comment: The United States supports the proposed GUL for vitamin B6.

Vitamin B12

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin B12	µg/100 kcal	0.1		0.5 1.4
	µg/ 100 kJ	0.025		0.12 0.3

Comment: We support a GUL for vitamin B12 because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The value proposed for the GUL takes into consideration variability among product forms (liquids and powders), inherent variability of vitamin B12 in milk-derived ingredients used in infant formulas, analytical issues associated with vitamin B12 measurements, losses over shelf life, and history of apparently safe use. The levels of vitamin B12 in infant formula are near the lower limit of detection for vitamin B12. A GUL of 1.4 µg/100 kcal will more reliably ensure that the analytical method accurately detects the level of B12 in infant formulas.

Pantothenic acid

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Pantothenic acid	µg/ 100 kcal	60 400		300 2000
	µg/ 100 kJ	15 100		75 500

Comment: The United States does not find reason to lower the minimum and GUL to levels below the Adequate Intake for infants (1.7 µg/day or about 340 µg/100 kcal). As proposed by the EC, the U.S. supports a minimum of 400 based on the AI for infants and a maximum of 2000 based on a lack of toxicity of pantothenic acid.

Folic acid

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Folic acid	µg/ 100 kcal	10		50
	µg/ 100 kJ	2.5		12

Comment: The United States supports the proposed GUL for folic acid.

Vitamin C¹²

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Vitamin C	mg/ 100 kcal	10		30 70
	mg/ 100 kJ	2.5		7 17

¹² Expressed as ascorbic acid

Comment: We support a GUL for vitamin C because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. In addition to its role as a nutrient, vitamin C functions as an antioxidant that is critical in stabilizing other nutrients during processing, storage, and use of infant formula. Its role as an antioxidant

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has become even more important with the addition of long-chain polyunsaturated fatty acids to infant formula. The value proposed for the GUL takes into consideration its function as a nutrient and as an antioxidant, variability among product forms (liquids and powders), analytical variability for vitamin C measurements, variability due to processing methods, losses over shelf life, and history of apparently safe use. It would not be prudent to set a GUL at a lower value, given the factors that must be taken into consideration in setting a GUL for vitamin C.

Biotin

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Biotin	µg/ 100 kcal	1.5		7.5 12
	µg/ 100 kJ	0.4		1.5 2.9

Comment: We support a GUL for biotin because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The value proposed for the GUL takes into consideration analytical variability for biotin measurements, losses over shelf life, and history of apparently safe use.

e) Minerals and Trace Elements

Iron

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Iron-cow milk and partial hydrolysate	mg/ 100 kcal	0.3 ¹³ 0.6	1.3	2.4
	µg/ 100 kJ	0.07 0.17	0.3	0.57

¹³In populations where infants are at risk of iron deficiency, iron contents higher than the minimum level of 0.3 mg/100 kcal may be appropriate and recommended at a national level.

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Iron-soy	mg/ 100 kcal	.45	2.0	
	µg/ 100 kJ	0.1	0.5	

Comment: We recommend deletion of footnote 13. The proposed minimum level for iron in milk-based formulas of 0.3 mg/100 kcal is acknowledged in the footnote to be insufficient for populations where infants are at risk of iron deficiency. We also recommend a minimum level for iron of 0.6 mg/100 kcal to avoid infant formulas that do not meet the nutritional requirements for all infants. Minimum levels for other nutrients have been set at levels that are thought to be adequate for all infants. We do not find a reason to make an exception for iron. Selection of 0.6 mg/100 kcal as the minimum level for iron also eliminates the need for a separate recommendation for soy-based formulas, as this minimum level is also greater than the minimum iron level proposed for soy formulas

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Rationale: Iron deficiency is the most common micronutrient deficiency in the world. It is associated with both acute and long-term consequences and the minimum level of iron in infant formula should be selected to help minimize the occurrence of such consequences. Although 0.3 mg/100 kcal may reduce the risk of anemia (the most severe stage of iron depletion), a level of 0.6 mg/100 kcal should provide adequate iron to maintain a higher level of iron status and improve iron stores to prevent later development of iron deficiency, not just prevent anemia. The level of 0.6 mg/100 kcal was recommended by the American Academy of Pediatrics as the minimum level for infant formulas to maintain iron status of infants.

Comment: Based on studies included in the IEG report, the IEG concluded that iron content higher than 1.3 mg/ 100 kcal would provide no additional benefit with respect to iron status and noted the potential for adverse effects on copper status. However, we question the value proposed for a maximum. We support a GUL for iron because data are not sufficient for a science-based risk assessment to establish a maximum value. In our March comments, we remarked on the history of apparently safe use with infant formulas that have stated label content of 1.8 mg iron/100 kcal. After we submitted that comment, we had an opportunity to examine the data provided by ISDI and the IFC. From the data provided, we noted that formulas with a stated label content of 1.8 mg iron/100 kcal, as expected, had analyzed levels that were higher than the stated label value. Based on these data, we propose a GUL of 2.4 mg/100 kcal, reflecting a history of apparently safe use for all types and forms of infant formulas.

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Calcium

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Calcium	mg/ 100 kcal	50	140	140
	mg/ 100 kJ	12	35	35

Comment: We support a GUL for calcium because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The proposed maximum values are suitable as guidance upper levels.

Phosphorus

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Phosphorus*—cow milk and partial hydrolysate	mg/ 100 kcal	25		90
	mg/ 100 kJ	6		22

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Total Phosphorus, soy	mg/ 100 kcal	30		100*
	mg/ 100 kJ	7		25*

***These total phosphorus values include the amount of phytate-phosphorus contained in soy protein-based formulas. Levels of phosphorus in milk-based products need not be adjusted to approach the GUL.**

Comment: We support a GUL for phosphorus because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. We suggest restructuring the phosphorus section of the table so that the GUL value for phosphorus will include all types of infant formulas and a history of apparently safe use.

Comment: We recommend addition of a footnote to explain that levels of total phosphorus include phytate-phosphorus found in soy protein-based formulas and that phosphorus levels in milk-based formulas need not be adjusted to approach the GUL.

Calcium:Phosphorus Ratio

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Calcium:Phosphorus-Ratio		1:1	2:1	

Comment: The United States supports the proposed range of calcium:phosphorus ratios.

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Magnesium

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Magnesium	mg/ 100 kcal	5		15
	mg/ 100 kJ	1.2		3.6

Comment: We support the GUL for magnesium as proposed.

Sodium

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Sodium	mg/ 100 kcal	20	60	60
	mg/ 100 kJ	5	14	14

Comment: We believe that maximum levels should be assigned for sodium, potassium, and chloride because of their critical role in maintaining electrolyte balance. Maximum levels for these minerals should be considered together because of the adverse effects that occur when electrolyte balance is disrupted.

Potassium

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Potassium	mg/ 100 kcal	50	160	160
	mg/ 100 kJ	12	38	38

Chloride

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Chloride	mg/ 100 kcal	50	160	160
	mg/ 100 kJ	12	38	38

Manganese

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Manganese	µg/ 100 kcal	1		50 100
	µg/ 100 kJ	0.25 0.24		24 or 12 24

Comment: We support a GUL for manganese because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. Inherent levels of manganese are quite high (and highly variable) in soy protein ingredients. Based on a history of apparently safe use, we suggest a GUL of 100 µg/ 100 kcal that would cover all types and forms of infant formulas.

Iodine

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Iodine	µg/ 100 kcal	10		75
	µg/ 100 kJ	2.5		18

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Comment: The United States supports the proposed GUL for iodine.

Selenium

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Selenium	µg/ 100 kcal	1		9
	µg/ 100 kJ	0.24		2.2

Comment: The United States supports the proposed GUL for selenium.

Copper¹⁴

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Copper	µg/ 100 kcal	35 60	80	190
	µg/ 100 kJ	8.5 14	49	45

¹⁴ Adjustments may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.

Comment: In our response to CL 2005/53, we questioned the need to lower the minimum value for copper to 35 µg/100 kcal. We continue to have concerns about a minimum value of 35 µg/100 kcal for copper in infant formulas. The basis for 35 µg/100 kcal is that this value is similar to breast milk content. The proposed minimum value of 35 µg/100 kcal is more than a 40% reduction from the value of 60 µg/100 kcal in the existing standard (CODEX STAN 72-1981 (amended 1983, 1985, 1987, 1997)), which is known to meet the copper requirement of infants. Without additional scientific evidence, we do not support this degree of reduction. We suggest that the minimum level for copper be maintained at 60 µg/ 100 kcal, a level that has scientific support and was the level recommended in the LSRO 1998 report.

Comment: We support a GUL for copper because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. With the availability of analytical data from industry reflecting the history of apparently safe use for all types and forms of infant formulas, we support the value of 190 µg/100 kcal. The proposed GUL takes into consideration the variability in inherent levels of copper in ingredients, variability among forms of infant formulas, analytical variability for measurement of copper, and history of apparently safe use.

Zinc

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Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Zinc, non-phytate	mg/ 100 kcal	0.5	1.5	2.4**
	mg/ 100 kJ	0.12	0.36	0.75**

****For soy protein infant formulas the minimum and maximum values for total zinc should be increased to 0.75 and 2.4 mg/100 kcal, respectively, because of the presence of phytate.**

****These total zinc values include the amounts added to soy protein-based formulas because of the presence of phytates. Levels of zinc in milk-based products need not be increased to approach the GUL.**

Comment: We support a GUL for zinc because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The values proposed take into account the need to add more zinc to soy formulas because of the presence of phytates in soy formulas. We suggest restructuring the zinc section of the table so that the GUL value for zinc will include all types of infant formulas and a history of apparently safe use.

Chromium

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Chromium	ng/100 kcal	35	77	
	ng/100 kJ	8.4	18.4	

Molybdenum

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Molybdenum	µg/ 100 kcal	1.4	2.8	
	µg/ 100 kJ	0.3	0.7	

Comment: Chromium and molybdenum have not been included for discussion by the EWG or the CCNFSDU up to this point and were not considered by the IEG. Scientific justification needs to be provided for addition of chromium and molybdenum to the Table of Essential Composition and for the proposed minimum and maximum values. Additionally, in the absence of sufficient data for a science-based risk assessment, information on analyzed levels of chromium and molybdenum in infant formulas would need to be obtained as a basis for setting GULs for these minerals.

f) Other Substances

Choline

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Choline	mg/ 100 kcal	7	50	50
	mg/ 100 kJ	1.7	12	12

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Comment: We support a GUL for choline because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The proposed maximum values are suitable as guidance upper levels.

Myo-inositol

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
Myo-inositol	mg/ 100 kcal	4	40	40
	mg/ 100 kJ	1	9.5	9.5

Comment: We support a GUL for myo-inositol because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas. The proposed maximum values are suitable as guidance upper levels.

L-carnitine

Nutrient	Unit	Minimum	Maximum	Guidance upper levels
L-carnitine	mg/ 100 kcal	1.2	N.S.	N.S.
	mg/ 100 kJ	0.3	N.S.	N.S.

Comment: We support “Not Specified” (N.S.) designation for L-carnitine because data are not sufficient for a science-based risk assessment to establish a maximum value for infant formulas, nor are they sufficient to establish a numerical GUL.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed under 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition **or to provide other benefits that are similar to outcomes of populations of breastfed babies.**

3.2.2 The suitability for the particular nutritional uses of infants and the safety of these substances shall be scientifically demonstrated. The formula ~~shall~~ **should** contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.

Comment: The word “should” should replace “shall”.

Rationale: It is not appropriate to say that addition of an optional ingredient is mandatory.

~~3.2.3 The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100 kJ) in the infant formula ready for consumption shall not exceed:~~ **Substances not categorized as essential nutrients for infants may be added in conformity with national legislation. The following list is not all-inclusive, but when the listed ingredients are added, the amount shall not exceed the following values:**

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Comment: We propose the above edits for section 3.2.3 to clarify that the table in 3.2.3 is not intended to be a comprehensive list.

Rationale: The category of optional ingredients should not imply that only the listed optional ingredients may be added to infant formulas, should future research support the inclusion of additional substances to infant formulas as optional ingredients.

Table: Optional Ingredients

Comment: Proposed additions of optional ingredients and proposed changes in maximum values in the Table are identified in bold.

Nutrient or Constituent	Unit, per 100 kcal	Maximum
Fluoride	Mg	60
Taurine	Mg	12
Total [added] nucleotides¹⁵	Mg	5-16
Cytidine 5'-monophosphate (CMP)	Mg	2.5 (6.5)
Uridine 5'-monophosphate (UMP)	Mg	1.75 (3.7)
Adenosine 5'-monophosphate (AMP)	Mg	1.50 (3.0)
Guanosine 5'-monophosphate (GMP)	Mg	0.50 (3.5)
Inosine 5'-monophosphate	Mg	1.00 (1.0)
Phospholipids	Mg	300
Docosahexaenoic acid (DHA) ^{15,16}		0.5% of total fatty acids

¹⁵**Nucleotides as the 5'-monophosphate may be added to infant formula to a maximum level of 16 mg/100 kcal. Use would include at least four nucleotides (two purine and two pyrimidine nucleotides) of the following five nucleotides: adenosine, guanosine and inosine (purines) and cytidine and uridine (pyrimidines), with a maximum of 45% of the total nucleotides added as purine nucleotides.**

Addition of Footnote 15

Comment: We suggest addition of the footnote shown above as a replacement for listing individual nucleotides and maximum levels for each nucleotide.

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Rationale: Variation in the levels of total nucleotides in cows' milk necessitates flexibility in the levels of addition of individual nucleotides. Specification of use of four of five nucleotides including both purines and pyrimidines would allow for formulation of products more consistent with the composition of human milk. See also the comment under Individual Nucleotides below.

⁴⁵¹⁶ If docosahexaenoic acid (22:6 n-3) is added to infant formula, arachidonic acid (20:4 n-6) contents ~~should~~ **must** reach at least the same concentration as DHA **but not exceed 0.75% of total fatty acids**. The content of eicosapentaenoic acid (20:5 n-3), ~~which is not a desirable constituent of infant formula but, can occur in~~ **which is present in some** sources of LC-PUFA, should not exceed the content of docosahexaenoic acid.

Comments on Footnote 45-16

Comment: In the first sentence, we suggest replacement of the word “should” by “must.”

Rationale: The intent of this sentence is to convey that addition of arachidonic acid is necessary if docosahexaenoic acid is added, thus the word “must” is appropriate.

Comment: A maximum for arachidonic acid should be added to the footnote. We recommend a maximum of 0.75% of total fatty acids as there are scientific data to support this level of addition.

Comment: For the second sentence, we suggest the above edits be made for clarity.

Comment: The 2005 IEG report suggested that conditions or limits are needed on the total amount of EPA that is present and the amount relative to other LCPUFAs in the infant formula. The footnote above states that the EPA content should not exceed the content of DHA (i.e., a ratio as high as 1:1 and as much as 0.5% of total fatty acids). However, the scientific rationale supporting this amount and ratio has not been explained and we again request clarification of the scientific rationale supporting this amount and ratio.

Comments on Optional Ingredients Listed in Table

Taurine:

Comment: Taurine should be kept in the table of Optional Ingredients as it has not been demonstrated to be an essential nutrient for humans.

Total Nucleotides:

Comment: We recommend use of the term “total nucleotides” and deletion of the word “added,” with consideration of a maximum level for total nucleotides of 16 mg/100 kcal.

Rationale: Use of the term “total ‘added’ nucleotides” is inconsistent with the general principle 5(b) in Annex II that total levels of a nutrient (both naturally occurring nutrients in the ingredients and added nutrients) should be taken into account when establishing

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minimum and maximum amounts. The maximum level of 16 mg/100 kcal for nucleotides takes into account both added and endogenous levels of nucleotides in cows' milk. Discussion supporting a maximum of 16 mg/100 kcal is included in comments that follow.

Comment: The U.S. position on nucleotides at the 27th session of CCNFSDU supported an allowable maximum level of total nucleotides in infant formula of 16 mg/100 kcal, rather than the 5 mg/100 kcal of added nucleotides that was proposed. Consensus about the level of nucleotides was not reached by the end of the meeting but the final report of the meeting does not reflect the difference of opinion about the nucleotide levels and shows only a level of 5 mg/100 kcal for total nucleotides in the table in Section 3.2.3. We request that the level of 16 mg/100 kcal for total nucleotides be included in the table in Section 3.2.3. The maximum level of 16 mg/100 kcal for total nucleotides takes into account both added and endogenous levels of nucleotides in cows' milk.

Comment: Questions about the maximum level of nucleotides raised by the United States in 2005 resulted in submission of additional information from experts. Based on this additional information and information provided at the 27th session of CCNFSDU by the Mexican Delegation, we recommended a maximum level of 16 mg/100 kcal in 2005. No new scientific information has become available since that meeting that suggests a need to reconsider this assessment and we continue to recommend that the maximum level of total nucleotides be 16 mg/100 kcal, which is at the upper range of the concentration in human milk. This level was also the maximum recommended by the LSRO Expert Panel in 1998.

Rationale: A maximum level of addition for added nucleotides of 5 mg/100 kcal was recommended by the Protein-Calorie Advisory Group (PAG) *ad hoc* working group meeting on clinical evaluation and acceptable nucleic acid levels recommended by the Scientific Committee on Food. The 5 mg/100 kcal level was based on methodology available at that time that measured only free nucleotides in human milk samples. Newer analytical methods consistently report higher amounts of nucleotides in human milk than previously reported, suggesting that these older methods underestimated the total amount of nucleotides in human milk. Human milk samples have been analyzed for total available nucleotide content across lactation stage, race and diet. Similar mean levels (~72 mg/L) have been reported for samples from Europe, Asia and the United States.

Of studies of infant formulas with levels of added nucleotides at or above 5 mg/100 kcal, only two studies have reported any negative morbidity data (upper respiratory infections), which is difficult to assess because of ambiguities in diagnostic criteria and reliance on reports by parents without physician verification. Several additional clinical studies of nucleotides in infant formulas at concentrations higher than 5 mg/100 kcal are available and results of these studies support a recommendation for a maximum level of 16 mg/100 kcal for total nucleotides. These studies have not reported occurrence of adverse effects in infants fed formulas containing total added nucleotides at or above 72 mg/L, including one study with a soy formula with nucleotide levels of about 300 mg/L (~45 mg/100 kcal). Levels of 16 mg/100 kcal of total nucleotides have been present in some infant

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formulas for more than a decade and there is also a long history of apparently safe use of soy formulas with nucleotide levels well above the 5 mg/100 kcal proposed by the IEG. With the exception of negative findings in two studies (which are based on ambiguous criteria and not verified by physicians), there is no evidence that suggests a safety concern for 16/mg 100 kcal as the maximum level of total nucleotides in infant formulas.

Comment: Because of inherent nucleotide levels of about 40-45 mg/100 kcal in soy infant formulas, there is no need to add nucleotides to soy infant formulas.

Individual Nucleotides:

Comment: Levels of individual nucleotides also needs further consideration. The current Codex proposal in the revised draft for Section 3 prepared by Germany for discussion at the 28th session of CCNFSDU includes specific levels for each of the five nucleotides (3 purines and 2 pyrimidines) that could be added as optional ingredients to infant formula. The Codex proposal could be simplified by using proportions of purines and pyrimidines rather than levels of each of the individual nucleotides. A maximum proportion of purines of 45% would encompass means + 2 standard deviations found in the published literature and the maximum individual levels currently proposed in the table in Section 3.2.3.

Long chain polyunsaturated fatty acids (LCPUFAs):

Comment: We support the proposed level of docosahexaenoic acid (DHA) not to exceed 0.5 % of total fatty acids.

Rationale: This proposed level is based on scientific data and we are not aware of new data to support a higher level of DHA.

3.3 Vitamin Compounds and Mineral Salts

Editorial Comment: Insert revised title: [Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children]

Purity Requirements

Editorial Comment: The section number “3.5” has apparently been inadvertently omitted.

3.6 Specific Prohibitions

The product and its components shall not have been treated by ionizing irradiation.

DRAFT POSITION ON THE PROPOSALS OF THE FOOD ADDITIVE WORKING GROUP FOR SECTION 4 (SECTION A AND B)

Comment: The Delegation of Switzerland is preparing a revised list of food additives for the standard, taking into account proposals made by CCFAC on this section for the draft revised standard for Processed Cereal Based Foods for Infants and Young Children and comments submitted to the 27th Session (ALINORM 06/29/26 para 109). We have not yet received a revised list from the Delegation of Switzerland, but anticipate having comments on it at the upcoming CCNFSDU session.

The United States continues to believe it is necessary for the CCNFSDU to establish working principles for establishing food additive provisions to guide a transparent decision-making process for the Committee and to facilitate progress on the food additive provisions of the standard. We expect to re-propose working principles for the Committee's consideration at its 28th Session.

We also note that the Codex Alimentarius Commission decided to defer consideration of adoption of food additive provisions in the GSFA for two infant formula categories (13.1.1 and 13.1.2), pending finalization of the draft standard for infant formula and submission of the additive sections for endorsement by CCFAC (ALINORM 06/29/41, para 49).

4.6 Carry-over of Food Additives

No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

- (a) of the food additives listed under Sections 4.1 to 4.4 of this standard within the limits of the maximum levels stipulated in this standard; and
- (b) [of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.]

Comment: The electronic work group (EWG) coordinated by the Swiss Delegation did not amend section 4.6 in its September 2005 report (CX/NFSDU 05/27/6—Add.1) and requested that CCNFSDU examine this issue carefully at its November 2005 Session. Because of time limitations, CCNFSDU was not able to consider this issue at the November 2005 meeting. In response to the request from the EWG, we suggest that the CCNFSDU consider incorporation of the text recommended by CCFAC for the processed cereal-based foods standard into the standard for infant formula (Section A), with appropriate editing as proposed below for reference to the infant formula standard and correction of the title of the Advisory List when it is finalized. We further note that the processed cereal based food standard was adopted at step 8 at the 29th Session of the Codex Alimentarius Committee.

“Only the food additives listed in this Section or in the Codex [Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979)] may be present in the foods described in section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CAC/STAN 192-1995, Rev. 5 (2004)).

The following food additives are acceptable for use in the preparation of ~~processed cereal based foods for infants and young children~~ **infant formula**, as described in Section 2.1 of this Standard (in 100 g **ml** of product, ready for consumption prepared following manufacturer’s instructions, unless otherwise indicated).”

Rationale: The language recommended by CCFAC and adopted by CAC for carry-over of food additives in the processed cereal based foods standard is appropriate for the infant formula standard as well.

DRAFT POSITION ON OTHER SECTIONS OF THE DRAFT REVISED STANDARD FOR INFANT FORMULA: SECTION A

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993) and the Guidelines for Use of Nutrition and Health Claims, the following specific provisions apply.

9.1 The Name of the Food

9.1.6 [Products containing not less than 0.5 mg Iron (Fe)/ 100 kilocalories shall be labelled "Infant Formula with added Iron"].

Or

[Products containing less than 0.5 mg Iron (Fe)/ 100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]

Comment: Iron levels in the infant formula standard remain to be established. Appropriate

label information should be discussed after the iron levels are established.

9.5 Information for Use

[Products in liquid form may be used either directly or prepared with safe ~~water~~ and previously boiled water before feeding according to directions for use. Products in powder form also requires safe and previously boiled water for preparation. **Directions for preparation and handling should be in accordance with Good Hygienic Practices.**

Comment: A statement should be added to Section 9.5 to incorporate reference to recent recommendations about use of good hygienic practices in preparation and handling of infant formula. These include the FAO/WHO Expert Consultation, the European Food Safety Authority report (2004), and the Codex Committee on Food Hygiene meeting report (2005).

Editorial Comment: Delete the word water from the first sentence for clarity.

9.5.1 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, ~~i.e. that formula remaining after feeding should be discarded, e.g., that powdered formula should be fed immediately after its reconstitution, and that all formula (whether ready-to-feed or reconstituted from powder or liquid concentrate) remaining in the bottle after feeding should be discarded,~~ shall appear on the label ~~[or in the accompanying leaflet].~~

Comment: We recommend addition of detail to include information about appropriate preparation, storage, and disposal of the product as shown above.

Rationale: The safe use of infant formula depends on correct preparation, storage, and disposal of the product.

Comment: We recommend deleting the language in 9.5.1 that would allow information to be contained only in a leaflet that would accompany the product.

Rationale: This information should be on the label, which is affixed to the can or container. An accompanying leaflet can easily become separated from the product.

~~9.5.2 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label [or in the accompanying leaflet].~~

Comment: If Section 9.5.1 is edited as shown above, we suggest that Section 9.5.2 be deleted.

Rationale: Section 9.5.2 does not add anything not already covered in Section 9.5.1, as edited above.

9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

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Comment: The square brackets should be removed from Section 9.5.3. If Section 9.5.2 is deleted, Section 9.5.3 should be renumbered to 9.5.2.

9.5.4 The directions should be accompanied by a warning about the health hazards of inappropriate preparation.]

Comment: The square brackets should be removed from Section 9.5.4. If Section 9.5.2 is deleted, Section 9.5.4 should be renumbered to 9.5.3.

9.6 Additional Labelling Requirements

~~9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of the product.]~~

Comment: The United States notes that the Guidelines for Use of Nutrition and Health Claims that were adopted at the 27th session of the Codex Alimentarius Commission (ALINORM 04/27/41, para 51) contain the following provision:

1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

Thus, the bracketed text as written in 9.6.6 is inconsistent with Section 1.4 which at a minimum provides for nutrition and health claims permitted by national legislation. Because of this contradiction, we recommend that 9.6.6 be deleted.

10. METHODS OF ANALYSIS AND SAMPLING

See Revised Table next page.

Comment: Table 10 remains to be updated for the draft revised infant formula standard, Section A. The following table incorporates AOAC methods that are current and applicable for use with infant formula.

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10. METHODS OF ANALYSIS AND SAMPLING

Analyte	Method	United States Comments on Methods
Dietary fibre, total	AOAC 991.43	Current method
Iodine (milk-based formula)	AOAC 992.24	Current method
Pantothenic acid	AOAC 992.07	Current method
Pantothen-ic acid	<i>The Analyst</i> 89 (1964)(1) 3-6,232	This is an old method (US Department of Agritulture. Agriculture Handbook 97 (1965)) that should not be used.
Vitamin A	AOAC 974.29	This is an old colorimetric method. Methods AOAC 992.04 or AOAC 992.06 should be used.
Vitamin A (retinol)	AOAC 992.04	Current method
Vitamin A (retinol)	AOAC 992.06	Current method
Vitamin A / carotenes	AOAC 942.15	Method 942.15 is a method for titratable acidity in fruit products. It is not suitable as a method for Vitamin A/carotenes.
Vitamin K	AOAC 992.27	Current method
Vitamin D (D ₃ , milk based infant formula)	AOAC 992.26	Current method
Vitamin E	AOAC 971.30	This is a colorimetric method dating from 1971 that should not be used.

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Analyte	Method	United States Comments on Methods
Vitamin E - milk-based formula	AOAC 992.03	Current method
Vitamin B12	AOAC 952.20	This is an old method (1952) that should not be used. Newer and more appropriate method is listed in next row of table.
Vitamin B12	AOAC 986.23	Current method
Vitamin B6	AOAC 961.15	This is an old method (1961) that should not be used. Newer and more appropriate method is listed in next row of table.
Vitamin B6	AOAC 985.32	Current method
Vitamin C	AOAC 967.22 AOAC 967.21	This titrimetric method is applicable only to vitamin preparations and should not be used with infant formulas. See next row of table for appropriate method.
Vitamin C	AOAC 985.33	Current method
Determination of Choline	AOAC 999.14	Current method
Determination of Vitamin K	AOAC 999.15	Current method
Detection of Irradiated foods	Codex general methods	
Determination of Lead	Codex general methods	
Calcium	AOAC 984.27	Current method
Chloride	AOAC 986.26	Current method

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Analyte	Method	United States Comments on Methods
Carbohydrates	method described in CAC/VOL IX Ed 1, Part III	
Crude protein	Method described in CAC/VOL IX Ed 1, Part III	
Fat	CAC/RM 55-1976	
Fatty Acids	AOAC 996.06	Current method and suitable for n-6 and -3 long-chain fatty acids
Fill of containers	CAC/RM 46-1972	
Folic acid	AOAC 944.12	This is an old method (1944) that should not be used. Newer and more appropriate method is listed in next row of table.
Folic acid	AOAC 992.05.	Current method
Linoleate (glycerides)	AOAC 922.06 AOAC 969.33 AOAC 963.22 AOAC 979.19	AOAC 922.06, AOAC 963.22, and AOAC 979.19 are older chromatographic and spectrophotometric methods that should not be used AOAC 969.33 is a method for preparation of methyl esters and not an analysis of fatty acids.
Linoleic acid	AOAC 992.25	Current method
Loss of drying	AOAC 934.01 AOAC 925.23	
Nicotinamide (non-milk) Nicotinamide (milk-based)	AOAC 961.14 AOAC 944.13	These are old methods (1961 and 1944) that should not be used. Newer and more appropriate method is

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Analyte	Method	United States Comments on Methods
		listed in next row of table
Niacin and nicotinamide	AOAC 985.34	Current method
Phosphorus	AOAC 986.24	Current method
Protein efficiency ratio (PER)	AOAC 960.48	Current method . Rat bioassay
Riboflavin	AOAC 970.65	This is an old method (1970) that should not be used. Newer and more appropriate method is listed in next row of table
Riboflavin	AOAC 985.31	Current method
Selenium	AOAC	Current method. If selenium is a required ingredient in infant formulas, an analytical method for measuring it must be available.
Sodium and potassium	ISO 8070 IDF 119A	These are old methods (1987) that should not be used. Newer and more appropriate method is listed in row below
Sodium and potassium	AOAC 984.27	Current method
Thiamine	AOAC 942.23	This is an old method (1942) that should not be used. Newer and more appropriate method is listed in next row of table
Thiamin	AOAC 986.27	Current method
Total dietary fibre	AOAC 985.29	Current method

SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AT STEP 6

AGENDA ITEM No. 4b

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, paras 112-129, Appendix IVB)
- Comments at Step 6 (CX/NFSDU 06/28/4, Add. 1)
- Section 4 food additive proposal prepared by Switzerland (CX/NFSDU 06/28/4, Add. 2) *not yet available*

At the last meeting, the Committee noted that it was necessary to discuss Section B concurrently with Section A and that it was desirable to have both sections of the standard at the same Step of development. The Committee advanced Section B for adoption at Step 5 by the 29th Session of the Codex Alimentarius Commission and the Commission adopted it at Step 5.

Please refer to the above documents for additional background.

DRAFT POSITION

I. GENERAL COMMENTS

We support the concept of Section B for formulas for special medical purposes intended for infants. We also support the approach that the items in Section A serve as the model for Section B with modifications as needed for Section B.

II. SPECIFIC COMMENTS

2. DESCRIPTION

2.1.1 Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula that complies with Section 2, Description of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding. **These products are to be used under the continuous direction and monitoring of a physician.**

Comment: We propose addition of the sentence shown above to the description of Formula for Special Medical Purposes Intended for Infants.

Rationale: For clarity and completeness of the description of Formulas for Special Medical Purposes Intended for Infants, it is important to draw attention to the need for these products to be used as a part of medical care.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1.3 The energy content and nutrient composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutrition requirements deriving from disease(s), disorder(s), or medical conditions(s), for whose dietary management the product is specially formulated, labeled and presented.

Comment: Although all of Section A3.1 is in square brackets, we anticipate that many of the nutrients in Part A may be taken out of square brackets at the 28th Session of CCNFSDU, thereby providing an opportunity for consideration of levels for these nutrients for Part B. Formulas for special medical purposes intended for infants differ substantially from routine infant formulas and from one other. Therefore, all references to Part A must be done with careful consideration.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed 3.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable for the infant and for the dietary management of his/her disease, disorder or medical condition.

Comment: We recommend that the content of Section 3.2 (Optional Ingredients) be established in Part A before considering this section in Part B.

4. FOOD ADDITIVES

Comment: The Delegation of Switzerland is preparing a revised list of food additives for the standard, taking into account proposals made by CCFAC on this section for the draft revised standard for Processed Cereal Based Foods for Infants and Young Children and comments submitted to the 27th Session (ALINORM 06/29/26 para 109). We have not yet received a revised list from the Delegation of Switzerland, but anticipate having comments on it at the upcoming CCNFSDU session.

The United States believes it is necessary for the CCNFSDU to establish working principles for establishing food additive provisions to guide a transparent decision-making process for the Committee and to facilitate progress on the food additive provisions of the standard. We expect to re-propose working principles for the Committee's consideration at its 28th Session.

We also note that the Codex Alimentarius Commission decided to defer consideration of adoption of food additive provisions in the GSFA for two infant formula categories

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(13.1.1 and 13.1.2), pending finalization of the draft standard for infant formula and submission of the additive sections for endorsement by CCFAC (ALINORM 06/29/41, para 49).

9. LABELLING

Comment: We anticipate that labels for formulas for special medical purposes intended for infants will need to be adapted according to the specific nature of these formulas. Provisions of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) will need to be incorporated, as appropriate, to reflect the medical purpose of these products.

In addition to the requirements under the Codex General Standard for Labelling of Prepackaged foods (CODEX STAN 1-1985 (Rev. 1-1991)) the following specific provisions apply:

9.1 The Name of the Food

Comment: Part A includes several provisions under 9.1. However, in ALINORM 05/28/26 and ALINORM 06/29/26, the Part B draft includes only the provision regarding the name of the product, shown as renumbered 9.1.2 below. We do not recall discussion that all of the provisions from A9.1 should not be included in B9.1 and recommend inclusion of 9.1.1, 9.1.2, 9.1.3, 9.1.4, and 9.1.5, as shown below.

A9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s).

Comment: We recommend addition of A9.1.1. to Part B.

Rationale: We recommend this addition to keep the Labelling Section of Part B parallel to the corresponding section in Part A. Section 9.1.1 from Part A shown above is applicable to Part B.

[9.1.4 **2** The name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage.]

Comment: The content of this section is consistent with the content of A9.1.2. and renumbering as 9.1.2 is parallel with the numbering in Part A.

[9.1.3 **Labels for** Formula for Special Medical Purposes Intended for Infants in which the essential characteristics involves a specific modification of the content or nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the **protein**, amino acid, fatty acid or carbohydrate profile, when necessary.]

Comment: We recommend the wording for 9.1.3 specify that this information be on the labels.

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Rationale: This information is critical for correct use of these types of products and needs to be stated on the label.

Comment: Protein should be included in the list of modifications to be described, as the modification in protein may not be captured by including information only on the amino acid profile.

[A9.1.4 If cow's milk is the only source of protein, the product may be labelled "**Infant Formula Formula for Special Medical Purposes Intended for Infants** Based on Cow's Milk".]

A9.1.5 A product which contains neither milk or any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

Comment: These provisions from Section A (A9.1.4 and 9.1.5) are not in square brackets and are applicable to Section B. We propose their addition, with the correct product name, as shown above.

9.5 Information for Use

See Section A9.5, **including 9.5.1, 9.5.2, 9.5.3, and 9.5.4.**

Comment: For greater clarity, we suggest the above edit.

Rationale: Some of the provisions from CODEX STAN 180-1991 pertain to use of formulas for special medical purposes intended for infants and should be included in B.9.5 as well as the provisions from Section A9.5. To avoid confusion and provide for consistent and parallel numbering in Section B9.5, reference should be made to the subsections of Section A9.5.

[9.5.5 Formula for Special Medical Purposes Intended for Infants shall be labelled with the information as specified in Sections 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.1, and 4.5.6 of CODEX STAN 180-1991.]

Comment: We recommend addition of 9.5.5 with reference to pertinent information in CODEX STAN 180-1991.

Rationale: Sections 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.5.1, and 4.5.6 of CODEX STAN 180-1991 contain information pertaining to the use of formula for special medical purposes intended for infants.

9.6 Additional Labelling Requirements

[9.6.1 ~~Formula for Special Medical Purposes Intended for Infants shall be labeled with the additional information specified in Sections 4.4.1, 4.4.3, 4.4.4, 4.5.1, and 4.5.5 of CODEX STAN 180-1991.~~ Information specified in Sections 4.5.2, 4.5.3, and 4.5.5 of CODEX STAN 180-1991 shall be included on the label or provided separately from the package.]

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Comment: We suggest listing of information for use in Section 9.5.5, as shown above and listing of additional information that does not pertain to use of the product in this section.

9.6.2 A prominent statement indicating that the product is intended as the sole source of nutrition shall appear on the label.

~~[9.6.3 In addition, the information specified in Sections 4.5.2, 4.5.3 and 4.5.6 of CODEX STAN 180-1991 shall be included on the label or be provided separately from the package.]~~

Comment: Information in Section 9.6.3 has been incorporated into Sections 9.5.1 and 9.6.1 as shown above.

~~{9.6.43~~ Labels and information provided separately from the package should not discourage breastfeeding, unless breastfeeding is contraindicated on medical grounds for the disease(s), disorder(s) or medical condition(s) for which the product is intended.

~~9.6.54~~ The product shall be labelled in such a way as to avoid any confusion between formula for special medical purposes intended for infants, infant formula and follow-up formula.~~†~~

Comment: These sections should be renumbered if Sections 9.5 and 9.6 are reorganized as suggested. We also suggest removal of square brackets on these sections.

10. METHODS OF ANALYSIS AND SAMPLING:

Comment: We note that the methods of analysis and sampling for infant formulas in Part A should also apply to Part B when the square brackets are removed from A.10.

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS

AGENDA ITEM No. 5

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, para 160)
- CL 2006/5-NFSDU (draft revised standard, March 2006)
- Comments at Step 6 CX/NFSDU 06/28/5

The Draft Revised Standard for Gluten-Free Foods has been considered during several sessions of the CCNFSDU without much progress because there was no consensus on gluten-free levels and the method of determination. At the 26th CCNFSDU session, the Committee noted that the Codex Committee of Methods of Analysis and Sampling had temporarily endorsed the R5 ELISA method for the determination of gluten.

At the last session, the Committee was unable to discuss the standard due to time constraints, and agreed to return the latest revision to Step 6 for comments and consideration at the next session.

DRAFT POSITION

I. GENERAL COMMENTS

The United States offers the following comments on the Draft Revised Standard for Gluten-Free Foods at Step 6. Our comments mainly focus on identifying questions and issues for the Committee's further consideration (including scope, definition of gluten-free, labeling, and certain inconsistencies), and take into account that the United States is in the process of rulemaking on gluten-free labeling.

II. SPECIFIC COMMENTS

Scope of this standard

The United States proposes that the Committee clarify the scope of this standard, and ensure that appropriate Codex texts provide for truthful and non-misleading "gluten-free" claims about the absence of gluten in foods that are and are not by nature free of gluten.

We would like to draw the Committee's attention to an apparent inconsistency between Section 1.1 and Section 2.1 with regard to this standard's scope. Section 1.1 states that this "standard applies to those foodstuffs and ingredients which have been especially processed or prepared to meet the dietary needs of persons intolerant to gluten." While Section 2.1b) appears to be consistent with this, referring to specific grain ingredients...which have been *rendered* "gluten-free", Section 2.1a) may be interpreted to refer to foods that are by nature free of gluten. In support of this interpretation, we note para 37 in ALINORM 97/26 which states:

"After an extensive discussion, the Committee agreed to define three groups according to their gluten content in the end product, with all figures in square brackets for further comments:

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- naturally gluten free foods (20 ppm)
- products which had been rendered ‘gluten free’ (200 ppm)
- any mixture of the two ingredients (200 ppm).”

The United States requests that the Committee clarify the scope of the standard and correct any related inconsistencies. We would support a scope that encompasses both foods rendered gluten-free and foods naturally gluten-free. This would require revisions to text in Sections 1.1 and 1.2 (Scope).

Definition of “Gluten-Free” (Sec. 2 and 3.1)

As noted above, the Committee proposed a decade ago to identify maximum gluten levels for three categories of foods, which represented: 1) “naturally gluten free foods;” “products which had been rendered ‘gluten-free’;” and 3) “any mixture of the two....” However, in subsequent Committee meetings, there was continued discussion about whether there should be one or two levels (e.g., ALINORM 99/26, para 36; ALINORM 01/26, para 30-32.).

Once the Committee has clarified this standard’s scope, we recommend further discussion of the text in Sections 2 and 3.1 considering, among other things:

- o Appropriate criteria for defining gluten-free;
- o Whether one or two levels are justified;
- o Whether to list oats with the other grains identified in Section 2 and 3.1; and
- o Additional areas where there may be a need to correct inconsistencies or update provisions.

Below are examples of issues for further discussion.

Criteria for defining gluten-free. The United States supports a definition of gluten-free that is scientifically sound, and facilitates the two Codex goals of protecting consumers’ health and facilitating fair international food trade. Specifically, the establishment of a maximum gluten level(s) in the definition of gluten-free should afford protection to persons who have celiac disease and are intolerant to gluten, and consider the sensitivity of the analytical method that would be used to verify compliance.

With regard to identifying a threshold that should protect persons who are intolerant to gluten, we emphasize the need for the Committee to consider the scientific literature to date, which raises concerns about the justification for the 200 ppm threshold proposed over a decade ago (refer to bracketed text in Sections 2.1b) and 3.1). For example, in a 2004 advisory opinion of the European Food Safety Authority¹, a scientific panel stated that “at present, clinical data are not sufficient to back up the [200] mg/kg threshold suggested” and that “the current figure of [200] mg gluten/kg food is arbitrary and does not include any safety factor.” The panel concluded that the proposed limit of 200 mg gluten/kg food therefore requires reconsideration. Recent studies that examined potential gluten exposure in individuals with celiac disease also

¹ European Food Safety Authority (EFSA). Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of allergenic foods for labelling purposes. (Request No EFSA-Q-2003-016). (Adopted 19 February 2004). pp. 40 and 44.

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bring into question whether the 200 ppm level would be protective, and accommodate individual variability in gluten sensitivity among those who have celiac disease (Collin, *et al*, 2004; Catassi, *et al*, 2005; Fasano, 2005).

With regard to the analytical methods that would be used to verify compliance of foods labeled gluten-free, we also emphasize the need for the Committee to consider the implications of the CCMAS temporary endorsement of the Enzyme-Linked Immunoassay (ELISA) R5 Mendez Method in establishing a maximum level for gluten in the definition of “gluten-free.” In particular, we note that the methods developed over the past decade since the 200 ppm was proposed are more sensitive (e.g., part of the rationale of one delegation’s support for the 200 ppm level in 1995 was that “no validated methods existed with a limit of determination below 160 ppm” (ALINORM 95/26, para 51).

Additional implications of updated methods of analysis. The United States notes that other provisions in the draft revised standard will likely need to be updated to reflect the updated text in Section 6 on methods of analysis. For example, we request that the Committee consider changing the references to “prolamins” in 2.1a) and the last sentence in 3.1 to “gluten”, and consider the need for any other modifications to the text based on the method for gluten determination that CCMAS temporarily endorsed.

Oats. The United States wishes to bring to the Committee’s attention that the word “oats” is stated in brackets (i.e., [oats]) in Section 2.1a) whereas the brackets around the word “oats” are missing in Section 2.1b) as presented in CL 2006/5-NFSDU. We believe that absence of brackets around the word “oats” in Section 2.1b) may have been an inadvertent omission.

Regarding the inclusion of oats in Section 2.1a), the United States notes that although a few recent reports in the scientific literature indicate that some individuals with celiac disease may be sensitive to the naturally occurring proteins in oats (Arentz-Hansen, *et al.*, 2004; Lundin, *et al.*, 2003), the findings of numerous published studies, including one that lasted 5 years, indicate that most individuals with celiac disease prefer and can tolerate a limited daily intake (e.g., 50 gm or less) of oats that do not contain gluten from wheat, rye and barley (Janatuinen *et al.*, 1995; Srinivasan, *et al.*, 1996; Hardman, *et al.*, 1997; Reunala, *et al.*, 1998; Janatuinen *et al.*, 2000; Janatuinen *et al.*, 2002; Storsrud, *et al.*, 2003). Therefore, the United States encourages the Committee to consider this information.

Description of other grains in 2.1. We further note that there appear to be certain inconsistencies in how the grains in 2.1 are described. For example, in 2.1a) there are references to all *Triticum* species, but this is absent from 2.1b).

Labelling (Section 4)

The current text of the draft revised standard reads as follows:

4. Labelling

The term “gluten-free” shall be given in the immediate proximity of the name of the product.

If the Committee decides that this standard's scope should include foods that are naturally free of gluten, then it might consider referencing the General Guidelines on Claims and adding a similar provision to Section 5.2 in the Codex Guidelines for Use of Nutrition and Health Claims to identify non-misleading language for such claims.

Specifically, section 5.1(v) of the General Guidelines on Claims (*CAC/GL 1-1979, Rev. 1-1991*), states:

5.1 The following claims should be permitted subject to the particular condition attached to each:

...(v) Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.

We further note a similar provision specific to nutrients in the Codex Guidelines for Use of Nutrition and Health Claims (*CAC/GL 23-1997, Rev. 1-2004*) which identifies how such a nutrient content claim should be expressed, i.e.:

5.2 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food."

Consequently, if the Committee decides to include foods that are naturally free of gluten in this standard, it could consider revising Section 4 to encompass the following new text identified in bold:

4.1 Foodstuffs Rendered Gluten-Free

The term "gluten-free" shall be given in the immediate proximity of the name of the product.

4.2 Foodstuffs Naturally Gluten-Free

In addition to the requirements of the Codex General Guidelines on Claims (*CAC/GL 1-1979, Rev. 1-1991*), where a food is by its nature free of gluten, the term describing the level of gluten should not precede the name of the food but should be in the form, "(naming the food), a gluten-free food".

Method of Analysis (Section 6)

The United States agrees with comments from some Codex members that suggest that the Committee consider clarifying and reorganizing certain text in this section.

References cited:

- Arentz-Hansen, H., *et al.* (2004). The molecular basis for oat intolerance in patients with celiac disease. *Plos Med*, 1:84-92.
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- Fasano, A. (2005). Presentation on *Prospective Studies*. Transcript of the Food Advisory Committee Meeting on *Advice on CFSAN's Draft Report: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food* held by the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, on July 14, 2005 in Greenbelt, Maryland, p. 141-145. Accessible at <http://www.fda.gov/ohrms/dockets/ac/cfsan05.html> on May 25, 2006.
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- Janatuinen, E. K., *et al.* (2002). No harm from five year ingestion of oats in coeliac disease. *Gut*, 50(3):332-335.
- Janatuinen, E. K., *et al.* (2000). Lack of cellular and humoral immunological responses to oats in adults with coeliac disease. *Gut*, 46(3):327-331.
- Janatuinen, E. K., *et al.* (1995). A comparison of diets with and without oats in adults with celiac disease. *N Engl J Med*, 333(16):1033-1037.
- Lundin, K. E., *et al.* (2003). Oats induced villous atrophy in coeliac disease. *Gut*, 52(11):1649-1652.
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- Srinivasa, U., *et al.* (1996). Absence of oats toxicity in adult celiac disease. *BMJ*, 313:1300-1301.
- Storsrud, S., *et al.* (2003). Beneficial effects of oats in the gluten-free diet of adults with special reference to nutrient status, symptoms and subjective experiences. *Br J Nutr*, 90(1):101-107.

**ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL
DIETARY USES INTENDED FOR INFANTS
AND YOUNG CHILDREN AT STEP 3**

Agenda Item No. 6

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, paras 130-140, Appendix V)
- CX/NFSDU 06/28/6 (Revised list prepared by Germany, August 2006)
- Comments at Step 3 CX/NFSDU 06/28/6, Add. 1 *not yet available*

At the last meeting, the Committee asked the Delegation of Germany to revise the list based on written comments and comments during the meeting. Member countries were requested to provide a list of their purity requirements, and to provide information that addresses how the nutrient compound satisfies the criteria in Section 2.1 for inclusion in the list. The Committee also discussed the scope of substances to be included in Table D.

Please refer to above documents for additional background.

DRAFT POSITION

The United States appreciates the efforts of the Delegation of Germany in preparing this revision of the advisory list for consideration by the CCNFSDU.

I. GENERAL COMMENTS

Advisory Lists A, B, and C

Column Headers in Tables A, B, and C

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The Delegation of Australia has proposed two alternatives for changes in column headers and subheaders that address our request for identification of products in the individual food standards. We believe that the most appropriate column header would be option (b) which identifies use of nutrient sources for the specific food standards and thus support changing the main header to “Use in Codex Food Standards Applicable to Infants and Young Children.” If option (b) is selected, it is then appropriate to subdivide the IF column into Part A and Part B columns. This organization makes it clear that the Part B: Formulas for Special Medical Purposes Intended for Infants is a part of the Infant Formula Standard. With the inclusion of Part B formulas as a subdivision in the Infant Formula column, we think it is appropriate for the Committee to consider whether a column for FSMP for young children is needed, as suggested by Germany.

Addition/Deletion of Nutrient Compounds in Tables A, B, and C

Several delegations recommended addition or deletion of nutrient compounds from Tables A, B, and C. Criteria for inclusion and deletion of nutrient compounds have been agreed upon and are listed in Section 2.1 of the Proposed Draft Revision of the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for the Use by Infants and Young Children (CX/NFSDU 06/28/6). We support the criteria in Section 2.1. Based on the comments submitted, it appears that a process may be helpful to facilitate Committee decisions for the addition or deletion of nutrient compounds. We suggest the following procedure:

1. For nutrient compounds that are listed in the existing Advisory Lists, the use of these nutrient compounds should generally be considered as justified, given that CCNFSDU and CAC previously endorsed their use. Members of the CCNFSDU that raise concerns about the continued listing of a specific nutrient compound are responsible for providing the data and information to the CCNFSDU explaining why the specific nutrient compound is no longer justified based on the criteria in Section 2.1. If a member raises a concern for a listed nutrient compound, the CCNFSDU will consider the information provided and decide whether there is justification to remove the nutrient compound from the list. The nutrient compound shall only be removed from the list if the CCNFSDU finds the evidence supports removal from the list.
2. For nutrient compounds that are not listed in the existing Advisory List, the members who propose the addition are responsible for providing data and information that justify the nutrient compound for use in products covered in the standard (e.g., infant formula or processed cereal based foods) based on criteria in Section 2.1. If a member objects to the proposal, this member is responsible for providing data and information to the CCNFSDU explaining why addition of the specific nutrient compound is not justified. The CCNFSDU shall consider all the data and information provided and decide whether there is reason to list the nutrient compound.

We also note that purity standards for some substances proposed for addition to the Advisory Lists include U.S. GRAS as a purity standard. We wish to clarify that we would not regard specifications in a GRAS notice as a national purity requirement.

Inclusion of Nutrient Compounds without International or National Purity Requirements

Several delegations requested that substances be included in the Advisory Lists even though they lack official purity requirements. We believe that nutrient compounds should meet the criteria for inclusion in Section 2.1 (including 2.1(c)) if they are to be included in the Advisory Lists. We are unaware of reasons why exceptions to those criteria should be allowed. We support the proposal of the Delegation of the EC that if nutrient compounds without purity requirements are to be removed, that it is advisable to make this decision when the list is finalized (ALINORM 06/29/26, para 136). We recommend that nutrient compounds without international or national purity requirements be kept in square brackets and believe that countries that want these substances to be listed should work to establish national purity requirements so that the substances will meet all of the criteria for inclusion. If any exceptions are considered, the reasons and process for doing so must be transparent and agreed upon by all countries.

Advisory List D

When the Committee reintroduced Advisory List D at the 26th CCNFSDU Session, the Committee specified that it include only substances that are: 1) food additives and 2) used for the purpose of nutrient carriers (ALINORM 05/28/26, para 128). We support the Committee's recommendation for limiting the scope.

We note that CCFAC has proposed a functional class for "carrier" (ALINORM 06/29/12, Appendix XV: Proposed Draft Revision of the Codex *Class Names and the International Numbering System*). The definition for carrier, currently in square brackets, includes nutrient carrier.

II. SPECIFIC COMMENTS

- 2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. **If a country proposes to add or delete a nutrient compound to a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.**

Comment: We suggest addition of a sentence as also shown above.

Rationale: It should be explicit that it is the responsibility of an individual/country to provide information when addition or deletion of a nutrient compound is proposed.

C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

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Comment: If footnote 8 p. 97 is added, it should include free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids.

Rationale: We are aware of internationally recognized purity requirements for free, hydrated, and anhydrous forms of amino acids, and their hydrochloride, sodium, and potassium salts. We are not aware of internationally recognized purity requirements for the calcium and magnesium salts of amino acids and suggest that purity requirements be identified if they are to be included in Advisory List C.

Comment: We recommend that the proposed use of L-glutamic acid and L-glutamine in infant formula and follow-on formula be removed from Advisory List C.

Rationale: This removal is warranted by the general provision that indicates that only essential amino acids may be added to these products to improve the quality of the protein.

D: ADVISORY LIST OF FOOD ADDITIVES ~~FOR SPECIAL NUTRIENT FORMS~~ FOR USE AS NUTRIENT CARRIERS

Comment: We recommend that the title be edited as shown above.

Rationale: This title incorporates the two specifications of the Committee for the scope of Advisory List D, i.e., that Advisory List D include only substances that are 1) food additives and 2) used for the purpose of nutrient carriers (ALINORM 05/28/26, para 128).

Comment: CX/NFSDU 06/28/6 includes three proposals for introductory paragraphs for Table D (i.e., language in previous draft, ISDI/Switzerland proposal, and EC proposal). We recommend deletion of the introductory paragraph from the previous draft and the introductory paragraph proposed by ISDI and Switzerland.

Rationale: CCNFSDU agreed that the introductory paragraph should refer only to food additives (ALINORM 06/29/26, para 137 and ALINORM 05/28/26, para 128). These two introductory paragraphs include use of “edible materials” and “substances” as nutrient carriers, which is outside the scope of Advisory List D agreed to by the Committee.

We propose the following edits to the EC proposal for consideration:

For reasons of stability and safe handling, some vitamins and **other** nutrients have to be converted into suitable preparations, e.g., ~~stabilized oily solutions, gelatine or gum arabic coated products, fat embedded preparations,~~ dry rubbed preparations. For this purpose, the food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used **as nutrient carriers**.

The maximum levels should be based on the amount needed to achieve the technical effect of a nutrient carrier under good manufacturing practice.

Where a food additive used as a nutrient carrier is also permitted in a Codex food standard for infants and young children for a different technological function, the

maximum level in the food should be determined by the function with the highest acceptable maximum use level under good manufacturing practice.

Rationale for suggested edits to the above introductory paragraph:

- Because vitamins are nutrients, the word “other” should be inserted in the first sentence to make this clear.
- We propose deleting the examples of “stabilized oily solutions”, “gelatine”, and “fat embedded preparations” because they do not apply to food additives used as nutrient carriers.
- The phrase “as nutrient carriers” should be added to the third and fourth sentences to emphasize that these food additives are used for the purpose of nutrient carriers.
- We propose that the CCNFSDU identify the criteria for determining maximum levels, and offer the above draft text for consideration (Refer also to related comments below about working principles for revision of food additive provisions).
- We propose the last sentence to clarify how the maximum level in a food should be determined when a food additive used as a nutrient carrier is also permitted for a different technological function (e.g., silicon dioxide may function both as an anticaking agent in processed cereal-based foods for infants and young children and as a nutrient carrier).

Scope of Substances to be Listed in Table D

Comment: We propose deletion of the first version of the table.

Rationale: This table lists substances that are outside the scope agreed to by the Committee. That is, the table should be limited to food additives used as nutrient carriers (ALINORM 05/28/26 para 128 and ALINORM 06/29/26 para 137). It is recognized that certain ingredients may also function as nutrient carriers, provided they are safe and suitable for their intended use according to the provisions in the respective standards (i.e., IF, FUF, PCBF, CBF) for 1) quality and purity of all ingredients, and 2) optional ingredients. Consequently, such ingredients are covered under the provisions for safe and suitable use in the respective standards and, therefore, should not be listed in Advisory List D.

Comment: The EC comments to CL 2005/53 indicated that not all of the Codex standards for foods intended for infants and young children list the following additives that may be used as nutrient carriers: gum Arabic (INS 414), silicon dioxide (INS 551), mannitol (INS 421), starch sodium octenyl succinate (INS 1450), and sodium L-ascorbate (INS 301). They proposed that these five food additives be listed in Table D in the Advisory List. The

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United States agrees that the Committee should consider listing these and any other food additives that meet appropriate criteria including technological need.

Format for Table D

Comment: We earlier proposed to expand the format of Table D to be consistent with the format of Tables A, B, and C. We note that use of an expanded format would involve collection and presentation of a large amount of specific information. Before continuing to suggest use of this format, we request that the Committee clarify if this specificity is needed or if use in all of the standards for foods for infants and young children could be listed in one column with footnotes to indicate if a nutrient carrier is not suitable for products in a particular food standard (e.g., infant formula).

Working Principles for Food Additive Provisions in Table D

At the last CCNFSDU session, the United States tabled a Conference Room Document that proposed working principles for the revision of food additive provisions in Codex Standards for Infants and Children. We believe that with slight adaptation, certain of these working principles are also applicable to finalizing the provisions for Advisory List D. For example:

Step 1: Functional Classes. As a first step, the CCNFSDU should resolve questions regarding the technological need for food additives *to function as nutrient carriers in foods included in each of the food standards*.

Step 2: Specific Food Additives. Once the need for *food additive nutrient carriers in foods in each of the food standards* has been resolved, then the CCNFSDU should address questions relating to specific food additives (i.e., revisions to the list of food additives and their maximum use level). This discussion should *consider, among other things*, the following principles:

- a. Within the needed functional classes, only additives assigned a full ADI by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are eligible for consideration in the standard.
- b. Food additives that have been allocated a numerical ADI should be assigned a numerical maximum level of use. The lowest level needed to achieve the technical effect under good manufacturing practice should be used for all food additives.

**PROPOSED DRAFT RECOMMENDATIONS
ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS
AT STEP 3**

AGENDA ITEM No. 7

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, paras 141-147)
- CL 2005/56-NFSDU (December 2005)
- CX/NFSDU 06/28/7 (draft recommendations prepared by France and responses to questions posed in above circular letter)
- Comments at Step 3 CX/NFSDU 06/28/7-Add.1 (*not yet available*)

At the last meeting, the Committee was unable to discuss the document in detail due to time constraints. The Committee agreed to return the proposed draft recommendations to Step 2/3 for redrafting by the Delegation of France in light of the comments received, for consideration at the next session.

The Committee agreed that further progress at its next session required careful consideration of several key issues identified in comments from Codex Members and Observers. It was agreed that a circular letter listing the questions to be addressed would be sent out for comment with a deadline of March 31 2006, to be addressed to the Delegation of France. These questions drew on a summary of issues identified by the Delegation of France which addressed, among other things, the scope of the document, relevance of safety concerns, the nature of scientific evidence required for health claims, and terminology.

Please refer to the above documents for additional background.

DRAFT POSITION

I. GENERAL COMMENTS

The United States would like to thank the French delegation for preparing this latest revision of the draft recommendations. We are pleased that some progress has been made on this document, and offer additional comments that we hope will contribute to further progress.

Scope and Nature of Recommendations.

The United States agrees that these recommendations should be read in conjunction with the *Codex General Guidelines on Claims* and the *Codex Guidelines for Use of Nutrition and Health Claims*. Accordingly, we support France's proposal to place these recommendations as an Annex to the *Codex Guidelines for Use of Nutrition and Health Claims*.

Moreover, to enhance these recommendations' usefulness to governments, we support France's proposal that these guidelines focus on elaborating a concise set of principles, and on identifying the common steps and logical sequence in substantiating health claims that are identified in

Section 5 (Step-By-Step Process). Accordingly, in the attached table, we offer a few suggestions for grouping related concepts and organizing existing text (as well as new text) in Section 4 under the following headings:

- 4. EVALUATION OF SCIENTIFIC EVIDENCE USED TO SUPPORT A HEALTH CLAIM
 - 4.1 Nature, Quality, and Scope of the Evidence
 - 4.2 Evaluation of the Total Body of Relevant Evidence
 - 4.3 Special Cases

In the June 2006 revised text, some specificity on the criteria for evaluating studies has been eliminated. We regard some of this information as valuable to make the document useful to governments. These proposed additions are noted in the attached table.

Terminology

To be consistent with the definition of a health claim in the Codex *Guidelines for Use of Nutrition and Health Claims*, we support the use of the phrase “food or food constituent” when referring to the substance of a proposed health claim in lieu of defining new phrases such as “property of a food” or “property”. We do not believe that the latter phrases have the same meaning as a “food or food constituent”, and thus are not consistent with the Codex definition of a health claim.

It appears that part of the rationale for proposing new terms is in response to one or more comments that proposed to extend health claims to “whole diets”. Consequently, we believe that it may be helpful to clarify in the Scope section that while these recommendations apply to health claims as defined in Section 2 of the *Guidelines for Use of Nutrition and Health Claims* (i.e., “any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health”), such health claims should take into account how the food or food constituent fits within the context of the total diet (Sec. 2.2.2, 2.2.3 and 7.4.6).

Specifically, the *Guidelines for Use of Nutrition and Health Claims* address the need to consider the total diet context in health claim language in the following provisions:

2.2.2 Other Function Claims- These claims concern specific beneficial effects of the consumption of foods or their constituents, in the *context of the total diet* (emphasis added) on normal functions or biological activities of the body....

2.2.3 Reduction of disease risk claims- Claims relating the consumption of a food or food constituent, in the *context of the total diet* (emphasis added), to the reduced risk of developing a disease or health-related condition.

Example:

“A healthful diet low in nutrient or substance A may reduced the risk of disease D. Food X is low in nutrient or substance A.”

“A healthful diet high in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A.”

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7.4. The following information should appear on the label or labeling of the food bearing health claims:

....

7.4.6 How the food or food constituent fits within the *context of the total diet* (emphasis added).

In summary, we believe that already adopted Codex provisions identify a food or food constituent as the subject of a health claim, but also provide for truthful and non-misleading health claim language that takes into account the context of the total diet.

II. SPECIFIC COMMENTS

Please refer to the attached table.

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p><i>Note: Bolded text identifies proposed text to be added, with the exception of headings in which shaded text identifies proposed text to be added. Proposed deletions are identified with strikeouts.</i></p>	
<p>PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS: RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS (Appendix 2)</p>	<p>We support the proposal that these recommendations be an Annex to the guidelines.</p>
<p>1. PREAMBLE:</p> <p>This Annex should be read in conjunction with the <i>Codex General Guidelines on Claims</i> (CAC/GL 1-1979 (Rev. 1-1991)) and the <i>Codex Guidelines for the Use of Nutritional and Health Claims</i> (CAC/GL 23-1997, Rev. 1-2004).</p>	<p>Propose minor edits to title</p>
<p>2. SCOPE:</p> <p>These Recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by the industry.</p> <p>They apply to health claims as defined in Sec 2.2 of the <i>Guidelines for Use of Nutrition and Health Claims</i> (i.e., “any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health”). Such health claims should take into account how the food or food constituent fits within the context of the total diet (Sec. 2.2.2, 2.2.3 and 7.4.6).</p> <p>They only address the nature and the quality of the scientific evidence supporting these claims.</p> <p>They include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations, although However, it is recalled that definite requirements on these matters have to be met and that they do not preclude consideration of specific food safety concerns (see section 4.3.2 3).</p>	<p>Propose clarify that the scope is consistent with the Codex definition of health claim (i.e., claims about a food or food constituent), but that such claims should also take into account the context of the total diet. (Refer to examples in 2.2.3)</p> <p>Propose delete “only” given that they also include safety considerations (see next sentence).</p> <p>Propose add text to encompass section on safety considerations.</p> <p>Propose renumber section on safety considerations (see rationale below).</p>

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>3. DEFINITION:</p> <p>—Hereinafter, the phrase “property of a food” or the term “property” are used to cover energy, nutrients, biologically active substances or components, ingredients, and any other feature or constituent of a food on which the health claim is based. This language may also be applied, where relevant, to a whole diet, as the diet itself may be assigned a common property of some of the individual foods making it up.</p>	<p>Propose delete this definition section and instead add the bolded text in the second paragraph of Section 2 (Scope) above for consistency with the health claim provisions and terminology in the Codex <i>Guidelines for Use of Nutrition and Health Claims</i>.</p>
<p>4.3.2. 3. SPECIFIC SAFETY CONCERNS</p> <p>When the claim is about a food or food constituent, the amount should not expose the consumer to health risks and the known interactions between the constituent and other constituents should be considered.</p> <p>The expected level of consumption shall not exceed any relevant upper levels of intake for food constituents.</p> <p>The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population^{2 3} and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources, when the same constituent is present in several foods, and for of nutritional imbalance due to changes in dietary patterns in response to consumers’ information laying emphasis on the food or food constituent property.</p>	<p>Propose move and renumber Sec. 4.3.2 in June 2006 draft in order to separate safety-related principles from principles for substantiating a proposed claim about a food/food constituent and a beneficial health effect.</p> <p>Propose add “food”</p> <p>Propose edit for clarification.</p> <p>Propose edits for clarification.</p> <p>Propose add “food constituent”</p>
<p>4. EVALUATION OF SCIENTIFIC EVIDENCE, USED TO SUPPORT A HEALTH CLAIM:</p> <p>After identifying national policies for health claims, the following principles apply to the evaluation of the scientific evidence for a proposed health claim.</p>	<p>Propose add introductory sentence to refer to the need to first identify national policies for health claims consistent with Step 1 in Section 5 and</p>

² Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1996. p.8.

³ European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals. SCF/CS/NUT/UPPLEV/11 Final. 28 November 2000. p.4

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
	with introductory text to the <i>Guidelines for Use of Nutrition and Health Claims</i> , and to clarify that this section focuses on <i>principles</i> for substantiating health claims.
<p>4.1 NATURE AND QUALITY, AND SCOPE OF THE EVIDENCE</p> <p>The following criteria should be applied in identifying, categorizing, and evaluating relevant studies:</p> <ul style="list-style-type: none"> – The scientific evidence studies should provide adequate characterization of the property of relationship between the food or food constituent to which and the health effect. is attributed and should ensure that the study groups are representative of the target group. Relevant studies include those that use appropriate measurements for the food or food constituent and health endpoint, that do not have significant study design flaws, and that are applicable to the targeted population for a health claim. Appropriate measurements for a health endpoint may include relevant validated biomarkers such as blood LDL-cholesterol for coronary heart disease. – 4.1 The totality of the evidence should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear. – All Health claims should primarily be based on evidence provided by well-designed human intervention (clinical) studies. A well-designed randomized, placebo-controlled clinical trial may demonstrate a causal relationship between a food or food constituent and health endpoint. Observational studies provide information about an association, but not causation. Animal model studies; and in vitro studies, etc. may be provided as supporting the knowledge base for the property food or food constituent–health effect relationship but should never not be considered 	<p>Propose slight revision to heading for 4.1 in June 2006 draft to encompass Steps 3 and 4 in Section 5, and to encompass and expand on the principles in 4.1 and 4.3.1 in the June 2006 draft.</p> <p>Propose edits consistent with Steps 4 and 5 in Section 5.</p> <p>Propose move 1st sentence from 4.3.1 in June 2006 draft and slightly revise.</p> <p>Propose add text to address considerations in identifying relevant evidence, such as the importance of identifying appropriate measurements for both the food/food constituent and health endpoint (including validated biomarkers).</p> <p>Propose move this bullet from section 4.1 in June 2006 draft here and slightly revise so that it addresses the identification of relevant scientific evidence to review.</p> <p>-Propose add “primarily” to first sentence for clarification. -Propose additional text to include observational studies and further distinguish between different types of human studies.</p> <p>Propose slight revision to this sentence.</p>

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>as sufficient per se to substantiate any type of health claim.</p> <ul style="list-style-type: none"> – The methodological quality of each type of study should be assessed, including study design and statistical analysis. For example, human intervention studies ÷ It should include an appropriate control group, characterize the target study groups’ background diet and other relevant aspects of lifestyle, the intake consistent with its intended pattern of consumption, the be of an adequate duration of exposure, and assess the influence of the food matrix and total dietary context on the property-health effect. Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientfiic community and with proper interpretation of “statistical significance”. 	<p>Propose reinsert principle from previous July 2005 draft to address the assessment of the quality of studies, consistent with the scope of this section.</p> <p>-Propose move text from 4.3.1 in June 2006 draft here with these revisions.</p> <p>Propose reinsert principle pertaining to statistical analysis from July 2005 draft.</p>
<p>4.2 EVALUATION OF THE TOTAL BODY OF RELEVANT EVIDENCE</p> <p>In evaluating the strength of the evidence, consideration should be given to the type, quantity and quality of relevant human studies, and consistency and reproducibility of results. For example:</p> <ul style="list-style-type: none"> – 4.1Evidence based on human intervention (clinical) studies should demonstrate a consistent association between the food or food constituent property and the health effect, with little or no evidence to the contrary. <p>Based on this evaluation, a government can determine if, and under what circumstances, a claimed relationship is substantiated, and if so, assess truthful and non-misleading language for the claim.</p>	<p>Propose new subheading to address principles in evaluating the strength of the total body of scientific evidence. This is consistent with Step 6 in Section 5 and with a separate section on this topic that was proposed in the July 2005 draft.</p> <p>-Propose add this principle to provide overview of key considerations in evaluating the strength of the total evidence.</p> <p>-Propose move this bullet from Section 4.1 in June 2006 draft here (with slight revision) since it appears to address evaluation of the strength of the totality of evidence.</p> <p>-Propose new sentence for additional context consistent with Step 6 in Section 5.</p>
<p>4.2 4.3 SPECIAL CASES:</p> <p>Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations, such as:</p>	<p>Propose renumber and move Section 4.2 in June 2006 draft here so that it follows discussion of the main principles in evaluating the scientific evidence for health claims (i.e, after Steps 1 through 6 in Section 5).</p>

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U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<ul style="list-style-type: none"> – Health claims bearing on fully recognized functions of nutrients and for which reports on clinical studies have been published in the scientific literature. – The totality of evidence may only comprise observational evidence, particularly for health claims involving a diet/food group/whole food—health effect relationships. – ‘Nutrient function’ claims may be substantiated based on generally accepted authoritative information that has been verified and validated over time. – 5.One could also use consensus reports or evidence-based dietary guidelines, providing these reports/guidelines are: prepared by an authoritative body, meet high scientific standards; are relevant to the claim; are relevant to the population in question; and are up-to-date. 	<p>Propose delete this bullet or reword. It appears similar to the next to last bullet on “nutrient function claims”</p> <p>Propose delete reference to diet/food group/whole food given these recommendations focus on claims about a food or food constituent.</p> <p>Propose include the entire text in last paragraph in Section 5 in June 2006 draft here, although we agree that it is also appropriate to briefly refer to this process in Section 5.</p>
<p>5. STEP-BY-STEP PROCESS</p> <p>It is possible to broadly outline a process for substantiation of health claims by national competent authorities that takes into account the general principles for substantiation. Such a process would typically include the following steps:</p> <ol style="list-style-type: none"> 1. Identify the standard of evidence for substantiation and other national policies for health claims. 2. Identify the proposed relationship between the food or food constituent property and the health endpoint for a health claim. 3. Identify appropriate measurements for the food or food constituent property and the health endpoint. 	<p>Propose add “national” to be consistent with the provisions in the <i>Codex Guidelines for Use of Nutrition and Health Claims</i> which state in the preamble that “Health claims should be consistent with national health policy, including nutrition policy and support such policies where applicable.”</p> <p>Propose add “or food constituent” for consistency in terminology with the <i>Codex Guidelines for Use of Nutrition and Health Claims</i>.</p> <p>Propose edits for consistency in</p>

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>4. Identify and categorise all the relevant evidence studies.</p> <p>5. Assess and interpret the evidence, study-by-study each relevant study.</p> <p>6. Evaluate the totality of the evidence across human studies and determine^{ing} if, and under what circumstances, a claimed relationship is substantiated.</p> <p>In order to substantiate a ‘reduction of disease risk’ claim, which offers the highest ‘degree of promise’ in the Codex Guidelines, a rigorous step-by-step evaluation of the available evidence should be required according to the outline given above.</p> <p>—Although stringent standards of scientific evidence should always be maintained, substantiation may be achieved through simplified processes for categories of claims with a lower ‘degree of promise’.</p> <p>As described in (new) Section 4.3, One could also use consensus reports or evidence-based dietary guidelines in special cases, providing^{ing} that specific criteria are met. these reports/guidelines are: prepared by an authoritative body; meet high scientific standards; are relevant to the claim; are relevant to the population in question; and are up-to-date.</p>	<p>terminology.</p> <p>Propose edits to Steps 4 and 5 for clarification and consistency with the principles proposed in Section 4.1.</p> <p>Propose add “human” to modify studies and change “determining” to “determine”.</p> <p>Propose delete these two paragraphs. The intended meaning of “degree of promise” is unclear, as well as how this concept relates to national policies for the substantiation standard(s) for health claims.</p> <p>Propose identify this alternative process here, but describe the principles more fully in the section on “Special Cases” above.</p>
<p>6. RE-EVALUATION:</p> <p>Health claims should be re-evaluated, after a certain period of time (possibly every 5-10 years) or following the emergence of significant new evidence that has the potential to alter previous conclusions about the food or food constituent- health relationship. In view of the frequency with which new evidence might emerge, a review may be unnecessary if the new evidence is unlikely to change the claim. Health claims should be re-evaluated only if new evidence calls into question the scientific validity underpinning the claim.</p>	<p>Propose add “or food constituent”.</p>

**DISCUSSION PAPER ON THE PROPOSALS FOR ADDITIONAL OR REVISED
NUTRIENT REFERENCE VALUES
FOR LABELLING PURPOSES**

AGENDA ITEM No. 8

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26, Para 29-40)
- CX/NFSDU 06/28/8 (Revised Discussion Paper to be prepared by South Africa)
not yet available

At the last meeting, the Committee agreed that an Electronic Working Group coordinated by the Delegation of South Africa should continue development of the discussion paper. It further agreed that the focus should be on principles for the establishment of NRVs for labelling purposes, and the need to establish NRVs for different population groups taking into account discussions and comments made at that session.

In March 2006, the Delegation of South Africa circulated a draft report to the Electronic Working Group that included excerpts from comments received in 2004 and 2005 and a discussion of terminology, and requested Working Group comments by June 30, 2006.

Please refer to the above documents for additional background.

DRAFT POSITION

The United States has not yet received the revised discussion paper prepared by South Africa, and consequently has not yet formulated a draft position on this document and agenda item. In the interim, we identify in two attachments excerpts from our June 2006 comments as a member of the Electronic Working Group that provide some preliminary thinking about this agenda item.

**CCNFSDU Electronic Working Group on Nutrient Reference Values
Excerpt of Comments from the United States
June 30, 2006**

The United States appreciates the efforts of the Delegation of South Africa to coordinate the CCNFSDU Electronic Working Group (EWG) on Nutrient Reference Values (NRVs) for food labelling purposes. The comments below respond to the March 2006 Working Group Coordinator request for comments on a draft report of this working group.

In the attachment, we propose general principles for establishing NRVs for vitamins and minerals, including factors to consider in selecting NRV population groups. We propose that the attached draft be considered as a starting point for discussions about the development of principles at the next CCNFSDU session. We further emphasize the importance of developing principles, especially given the complexity of any effort to establish or update NRVs.

One proposed principle is that science-based reference values for daily intake of vitamins and minerals that are established by authoritative scientific bodies be used as the basis for the NRVs. We assume that once the Committee has reached agreement on general principles for establishing the NRVs and on the NRV population group(s), a next step would be the development of tables that identify the science-based reference values from suitable references according to agreed upon principles. Another proposed principle is that a government may select to use the Codex NRVs, or alternatively, establish food label reference values that take into account additional factors specific to a country or region.

Taking into consideration the attached draft principles for selecting NRV population groups, we propose that at a minimum, the Committee consider updating the general population NRVs in the *Codex Guidelines for Nutrition Labelling*. In updating the general population NRVs, the Committee will likely consider the age range for which these values are intended (e.g., persons 3 years and older or persons 4 years and older). In support of the former age range, it was pointed out at the 26th CCNFSDU session that certain Codex texts define “young children” as persons age 12 to 36 months. On the other hand, the Committee will want to also consider that some reference values for recommended intakes and/or upper levels of intake have been established for the age range 1 *through* 3 years⁴. While consideration of the frequently lower recommended intakes for the 1 through 3 year age range would not impact on a general population NRV if based on adult recommended intakes, the frequently lower upper intake levels could have implications for establishing a general population NRV in cases where the adult recommended intake value(s) exceed the upper level of intake value(s) for children 1 through 3 years of age.

We further note that since the establishment of the current NRVs, the list of nutrients with science-based reference values for daily intakes has not only increased, but the level of complexity in identifying values for individual nutrients has also increased. For example, the 1998 joint FAO/WHO expert consultation on human vitamin and mineral requirements identifies iron recommended nutrient intake values at four levels of bioavailability for 17 different life stage groupings (i.e, age, gender, pregnancy and lactation) for a total of 68 values. In addition, any updates to the current NRVs will need to also take into account recent science-based values for upper levels of intake. Thus, the Committee may wish to consider this increased complexity in decisions about the process for updating the general population NRVs and about whether to establish values for additional NRV population groups.

Scope of Nutrients to be Updated

⁴ Human Vitamin and Mineral Requirements. Report of a Joint FAO/WHO Expert Consultation. Bangkok, Thailand. 2002; and Dietary Reference Intakes Tables-The Complete Set. Institute of Medicine, National Academy of Sciences. <http://www.iom.edu/subpage.asp?id=7292>

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We suggest that the Committee consider at the next session how the protein NRVs will be updated. We note that the list of nutrients in the Codex *Guidelines for Nutrition Labelling* (CAC/GL 2-1985 (Rev.1-1993)) includes protein in addition to vitamins and minerals. While the report of the 26th CCNFSDU session indicated that the Committee welcomed the offer of FAO and WHO to address the establishment of NRVs in the framework of future expert consultations on carbohydrates (2006) and fats and oils (date to be determined), the report did not specifically address how the protein NRVs would be updated (ALINORM 05/28/26, para 38-40).

If the Committee decides to update the protein NRVs, we believe this requires consideration of additional principles specific to establishing NRVs for macronutrients, and note that this will add to the complexity of the effort.

Attachment

Draft General Principles for Establishing Nutrient Reference Values for Vitamins and Minerals in the *Codex Guidelines for Nutrition Labelling*
(for consideration by the CCNFSDU)

A. Purpose of Food Label Reference Values for Nutrients

Food label reference values for nutrients provide a basis for expressing nutrient content in nutrition labelling, and may also provide a basis for criteria for certain nutrition and health claims. Their main purpose is to help consumers compare the nutrient content of different food products and to determine the contribution of a food product to an overall healthful diet.

B. Governments' Selection of Food Label Reference Values for Nutrients

The establishment of Codex Nutrient Reference Values (NRVs) for food labelling purposes is intended to facilitate the goals of protecting consumers' health and fair international trade in food. A government may select to use the Codex NRVs, or alternatively, establish other food label reference values that take into account additional factors specific to a country or region. For example, at the national level, values for the general population may be based on population-weighted averages of science-based reference values for daily intakes of the different age-gender groups. In addition, the bioavailability of food sources for a nutrient such as iron in a country may influence recommended intakes of that nutrient and consequently, a country's food label reference values.

C. Selection of NRV Population Groups

In selecting population groups for NRVs, the following factors should be considered:

- a. the main purpose of food label reference values for nutrients;
- b. the anticipated use of the NRVs, given that some governments may establish country or region-specific food label reference values, and the resources required for the Committee to develop one versus multiple sets of science-based NRV values from complex data sources.
- c. how food products are marketed (i.e., the extent to which products are marketed to the general public versus specific population groups) and practical considerations such as the amount of food label space; and
- d. the lifestage (i.e., age, pregnancy and lactation) and gender that correspond to science based reference values for both: 1) recommended intakes and 2) upper levels of intake.

D. Selection of Science-Based Reference Values for Daily Intakes as the Basis for Establishing NRVs

1. Science-based reference values for daily intake of vitamins and minerals that are established by authoritative scientific bodies and that reflect independent reviews of the science shall be used as the basis for the NRVs. Higher priority may be given, as appropriate, to more recent references from authoritative scientific bodies.
2. The NRVs shall be based on the following type of science-based reference value for daily intake:

Option 1:

[values that meet the requirements of 50 percent of an apparently healthy population for those nutrients for which estimated average requirements have been established]

or

Option 2:

[values that meet the requirements of 97 to 98 percent of an apparently healthy population]

3. The establishment of NRVs for the general population aged ____ and older shall be based on science-based reference values [excluding values for pregnant and lactating women] for:

Option 1:

[adult males and females equally weighted]

or

Option 2:

[the age-gender group(s) with the highest value]

They should also take into account science-based values for upper levels of intake.

Note: If the Committee decides to establish NRVs for other population groups such as infants and/or young children, general principle(s) can be added to address how these values will be derived.

**DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS
TO THE WORK OF THE CCNFSDU**

AGENDA ITEM No. 9

BACKGROUND

Reference:

- Report of the 27th CCNFSDU Session (ALINORM 06/29/26 paras 148-153)
- CX/NFSDU 06/28/9 (Revised discussion paper to be prepared by Australia) *not yet available*

At the last meeting, the Delegation of Australia introduced a discussion paper and referred to progress made in an *ad hoc* working group. Australia highlighted the work done in the Commission and other committees in this area, and emphasized that following the spirit of the current draft Strategic Plan 2008-2013 much more work should be done in order to complete this activity by 2013.

Due to time constraints, the Committee did not have a substantive discussion on this matter, and agreed to establish an Electronic Working Group to further develop the document for consideration at the next session. The Committee agreed that the Working Group should further consider issues raised in the agenda paper and present recommendations, and submit a proposal for new work to develop risk analysis principles and possibly guidelines for application to the work of the CCNFSDU.

Please refer to the above documents for additional background.

DRAFT POSITION

The United States supports the development of risk analysis principles and/or guidelines for application to the work of this Committee, based on consideration of the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (*pp. 101-107, Codex Procedural Manual, 15th ed.*). The development of such a document is consistent with the Commission's request at the 26th session of the Codex Alimentarius Commission that relevant Codex committees develop or complete specific guidelines on risk analysis in their respective area, for inclusion in the Procedural Manual, as recommended in the Commission's Action Plan (*para 147, ALINORM 03/41*).

The United States has not yet received the revised discussion paper, and anticipates that it will have additional comments on this agenda item at the next CCNFSDU session.